The views expressed in this publication are those of the authors and not necessarily those of the PSRP, the Department of Health or the NPSA.

As some projects are ongoing, a second edition of this publication is planned for early 2010.
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Forward

By Professor Richard Lilford
Portfolio Director

Early on a Saturday morning in December 1967, a surgeon in Cape Town settled down to write up his operation notes. As he was doing so, the anaesthetist suggested that the hospital administrator should be informed of the nature of the operation that had taken place. So Christiaan Barnard phoned the sleeping administrator to tell him that the world’s first successful heart transplant had been carried out a few hours before. Later that day, a school boy in Johannesburg was transfixed as the news broke all over the world.

In fact, I find the events of that Saturday night as awesome today as I did then. This is because the operation, if taken out of its historical context, is even more audacious than it seemed at the time. René Alamberti described the 1950’s and 60’s as the heroic age of medicine – these decades gave us cancer chemotherapy, contraception, haemodialysis, organ transplantation, artificial respiration, cardiac bypass, pre-natal diagnosis, rhesus prophylaxis, ultrasound imaging, ligand binding assays, to mention just a few.

But all these medical advances carry with them new dangers – opportunities to let a patient down. Each treatment discovery carries with it a string of contingent errors. A new medicine may not be given when is indicated, given when it is contra-indicated or administered at the wrong dose, by the wrong route, for too long (or short) a period, etc, etc. As a result, some error is almost inevitable – if a person experiences n procedures, each with an x probability of error, the probability of escaping completely unscathed is $x^{n-1}$. If you check into an intensive care unit, you are almost guaranteed to fall foul of error since n approximates 1000 in this setting, according to Timor-Tritsch.

The heroic age in which a surgeon may inform the administration of a radical new therapy only after it had been introduced into practice is past. Now we need to proceed in a more deliberate way, introducing new treatments in a planned way and mitigating the errors they spawn. And that cannot be achieved by sanctions for the recalcitrant nurses, doctors, physiotherapists, etc. Rather, the systems within which they are educated and work need to be adapted to prevent errors. We need to trap the errors that beget errors.

The Patient Safety Research Programme set out to provide evidence on how the system can be strengthened to reduce the risk of error and resulting harm. This booklet is an account of this research. The programme has also increased capacity for patient safety research and focused attention on methodological issues. The epistemology of patient safety is “a work in progress”. However, one thing appears clear – there is no one size fits all solution for the evaluation of interventions designed to improve patient safety. This booklet exemplifies this eclecticism as well as providing practical information for the service. It is now seven years (and £6m) since the Chief Medical Officer inaugurated this research programme and the time has now come for you to judge the results.

Professor Richard Lilford
Portfolio Director

February 2009
Chapter 1 – Response to ‘An Organisation with a Memory’

1.1 Introduction by

Professor Aneez Esmail
Associate Vice-President & Professor of General Practice, University of Manchester

It’s almost eight years since the Chief Medical Officer produced his seminal report ‘An organisation with a memory’ which launched the patient safety movement in the UK. It’s self evident that if we are to improve our organisational memory, then we need a comprehensive understanding of the extent of the problem, not only so that we can plan interventions but also identify whether our interventions are working.

In the series of four papers in this section, the authors attempt to paint the scenery as regards the extent of the problem – or more accurately the epidemiology of error – especially in relation to obstetrics and primary care. Esmail and colleagues review the information from an analysis of claims data in both secondary and primary care. Ashcroft identifies the extent of the failures in childbirth care and Kurinczul attempts to identify the extent of the problem related to neonatal injuries, commenting on the fact that we still have insufficient information to understand the extent of the problem. Finally, Strachan considers the value and effectiveness of training showing that relatively straightforward interventions can have a significant outcome in preventing errors in childbirth.

One of the key messages from ‘An Organisation with a Memory’ was that focussed attention on identified problems will result in safer patient care. The failure to utilise medico-legal information and continuing confusion over defining what constitutes neonatal injury prevents concerted action because we lack information on important pieces of the puzzle. It’s an indictment of the early history of the NHS that even though we have been collecting information on medico-legal cases and on neonatal injury since its inception, we failed to do this in manner which enabled us to effectively identify and act on a range of problems. Similarly, knowing that labour wards are one of the areas in hospital where errors can have disastrous consequences and yet failing to prevent them through training isn’t exactly rocket science. Yet it’s the task of research to identify ‘the known knowns’ and throw light on the things that ‘we know that we do not know’. That has to be the basis on which we move forward and this group of research papers are a suitable response to one of the challenges that the CMO identified – namely to identify the nature and magnitude of system failure and medical error.
1.1.1 Patient safety – what claims against the NHS can teach us
Professor Aneez Esmail

Key Messages:
- Existing data on clinical negligence cases has not been collected with the aim of improving patient safety so may be difficult to use for that purpose
- However, it is possible to use data from clinical negligence litigation databases to give important insights to the causes and development of errors
- Claims data can help provide information about procedures and specialties at high risk of litigation, but can never give reliable data about the underlying incidence of adverse outcomes
- Data on clinical negligence cases is hard to access and is sometimes kept in unstructured paper records, scattered across different organisations, fragmented across multiple sets of records, and collected without using common definitions or standards
- To make full use of the potential of these databases, it would be necessary to introduce a number of changes in the way in which they are currently structured and managed
- The coding of diagnoses, procedures, errors and outcomes would need to be performed in a much more comprehensive and consistent way to allow more detailed analyses to be performed and permit more accurate identification of areas with error rates significantly above or below average
- Systems for identifying patients who are particularly at risk, for whatever reason, and prioritising their treatment and focusing on their care in more detail help to prevent errors.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

An obvious source of information on adverse events is the extensive set of data gathered by NHS organisations and other agencies about cases of clinical negligence litigation, where patients and their families sue NHS organisations because they believe they have received negligent care.

Aims of the Study:
The study’s main aims were to:
- carry out an audit of data quality of litigation databases held by four medical defence/litigation organisations and a NHS trust to describe their structure, how they were categorised, strengths and weaknesses, and their potential for informing threats to patient safety
- describe the history and development of errors held in the litigation databases
- develop guidance for future collection of information in the litigation databases so that this information can feed into a broader system for reducing harm
• identify a representative sample of cases covering primary care, obstetric care, mental health and non-obstetric hospital care from which more detailed root cause analysis could be carried out
• identify key relevant management problems and contributory systems factors
• identify common and divergent action points
• produce recommendations to the Nation Patient Safety Agency and Department of Health on areas of concern where patient safety is compromised.

About the Study:
The researchers got permission to access data from four medical defence/litigation organisations – the NHS Litigation Authority (NHSLA), Medical Defence Union (MDU), Medical Protection Society (MPS), Capsticks solicitors – as well as from Oxford Radcliffe Hospitals NHS Trust. Using this data, they analysed the information to look at clinical negligence cases and explore how useful these databases were in learning lessons for patient safety and improving patient care. They analysed around 500 cases from each of the four organisations. The second phase of this research focused on what caused these cases and how avoidable/preventable certain types of adverse clinical events that resulted in litigation practice were in four specialties – general practice, general surgery and medicine, psychiatry, and obstetrics.

Practical findings:
The researchers produced three reports which make up this piece of research. These are:
• an analysis of databases of clinical negligence litigation to study the causes and development of errors
• an analysis of claims for clinical negligence to learn lessons
• review of claims in four specialties looking at case studies.

Common errors:
The researchers found that the most common error in primary care (in 50% of cases) was a failure or a delay in diagnosis. Other common errors included medication prescription errors, failure or delay in referral and failure to warn of or recognise the side effects of medication. The most common recorded outcome of such errors in primary care was the death of the patient (in 21% of cases). Other common outcomes included deterioration in clinical condition (6%) and unnecessary pain (4%). The most common errors in secondary care were failure or a delay in diagnosis (21%) and the unsatisfactory performance of a procedure (18%). Other common errors included unintended injury during a procedure (5%) and various problems around vaginal delivery (5%). The commonest recorded outcome of these errors in secondary care was unnecessary pain (11%), death (10%), cerebral palsy (7%), brain damage (6%) and a need for further surgery or treatment (5%). The researchers calculated incidence ratios of errors in relation to total consultations (primary care) and total hospital episodes (secondary care).

From these they found that in primary care, the incidence ratio of error was highest for patients in groups with neoplasms, congenital problems, and complications of pregnancy. Analysis showed that certain conditions – such as septicaemia, meningococcal infection, appendicitis and various neoplasms – had a high incidence ratio of error/claim. In the hospital setting, the incidence ratio of error was highest in the specialties which traditionally produce the most claims – accident and emergency, obstetrics and trauma and orthopaedics. Similarly, the incidence ratio was highest for cases to do with diagnosis concerning pregnancy and injury/trauma. The researchers found the quality of data in the available databases of clinical negligence litigation cases varied widely, and between 2% and 41% of original samples had to be excluded due largely to a lack of essential information needed to code or categorise the case.

Potential of claims reviews:
The limitations of reviewing claims against the NHS are significant, according to the researchers, and only around 70% of claims looked at in this work were suitable for full review. These limitations
include:

- a lack of common data
- bias towards more severe injuries
- problems in reliability of judgements
- clinical notes and expert reports were of varying quality
- outcome and hindsight bias
- key information was sometimes missing
- unrepresentative nature of claims.

The researchers said claims review was only one of a number of approaches to studying adverse events such as systematic record review. Claims review can highlight those procedures and specialties at high risk of litigation, but cannot give reliable data about the underlying incidence of events. Although claims review can be useful as one way of understanding error and adverse outcomes, says the paper, there should be certain preconditions met and certain standards of data quality and organisation. These minimum requirements include:

- either the condition under investigation is sufficiently rare not to be easily detectable by other means, or claims data offers additional information not available otherwise
- other methods of investigating this class of problem have been assessed and claims review has been found to provide additional valuable information
- cases are selected and analysed as soon as possible after the incident occurred
- more attempt is made to understand the patient’s perspective and experience as this is, potentially, a strength of claims data compared with other methods
- due consideration is given, where possible, to defining an appropriate control group
- claims data is assembled in a central database and is checked and subject to quality control at the time of entry to the database
- results of claims review are treated as working hypotheses and subject to further investigation in more formal studies
- claims review is used only as part of a more general quality and safety improvement strategy.

**Claims within specialties**

The researchers carried out four reviews in different specialties – primary care, medicine and surgery, mental health, and obstetrics. They selected cases from different databases and experienced clinicians reviewed samples of cases from each of the four specialty areas choosing themes – such as suicide in mental health patients – that were of clinical and medico-legal importance. From the final 152 cases finally chosen, they made the following observations.

**General Practice**

- Systems failures related to organisation, such as poor record keeping and lack of communication between primary and secondary care, remain an important cause of adverse events
- Computerised decision aids may help diagnosis of rare diseases such as diabetes in children
- Robust systems of care for the ongoing management of diabetes in adults are vital
- Primary care trusts need to be able to access information about rare diseases easily.

**Surgery and general medicine**

- Taking the patient’s history and clinical examination remain vital to the art of diagnosis
- Assessment at the time of discharge and clear guidelines to GP’s and to clinical staff in follow-up clinics is an important safeguard
- An awareness of the changing epidemiology of previously rare diseases, such as tuberculosis, remains important
- Specialists must seek advice on cases outside of their area of interest
- Junior staff should not be taking full responsibility for assessment of patients in outpatient clinics.
Mental Health
- Observation of patients who have been sectioned needs to be defined in care plans
- Psychiatric referral needs to be more easily accessed so that at risk patients can be seen quickly
- Nursing notes need to be amalgamated into medical notes so that a full assessment can be made including a list of observations, past history, current stresses and symptoms
- More and better training needs to be put in place for diagnosis
- Emergency resuscitation equipment needs to be available, in working order and staff trained to use it.

Obstetrics
- Further training in interpretation of cardiotocography (CTG) – the method of measuring the foetal heartbeat and contractions during childbirth – may be beneficial in avoiding adverse events, to ensure correct use of these monitors
- Failure to adhere to guidelines may be an important cause of adverse events
- Problems within the system of care, with doctor-patient relationships and with teamwork/supervision were noted
- All levels of staff can be responsible for poor judgement.

Summary of main findings:
- Quality of data in available databases of clinical negligence litigation cases varied widely
- Integrated clinical records and strong systems for communication between different healthcare professionals help to prevent errors which arise as a result of knowledge not being shared or communicated properly
- Many errors begin with clinical assessment, history taking, using routine monitoring equipment and documentation of a patient’s problems
- The most common error in primary care (representing 50% of cases) was a failure or delay in diagnosis, followed by medication prescription errors, failure or delay in referral and failure to warn of or recognise side effects of medication
- The commonest recorded outcome of these errors in primary care was the death of the patient (in 21% of cases)
- The most common errors in secondary care were failure or delay in diagnosis (21%) and the unsatisfactory performance of a procedure (18%)
- The commonest recorded outcome of these errors in secondary care was unnecessary pain (11%), death (10%), cerebral palsy (7%), brain damage (6%) and a need for further surgery or treatment (5%).

Conclusions, recommendations and implications for practice and policy:
- Data on cases of clinical negligence could and should be used much more fully to learn lessons for patient safety, if it were more consistently gathered, reported on and applied
- To make full use of the potential of these databases, it would be necessary to introduce a number of changes in the way in which they are currently structured and managed
- NHS organisations should consider agreeing to have common and systematic coding of data on clinical negligence cases for areas such as diagnoses, procedures, errors and outcomes, to make it easier for information to be analysed and allow more accurate identification of areas with error rates significantly above or below average
• There is a need to develop a common minimum data set of information on cases of clinical negligence usable in NHS bodies and medico-legal organisations

• Mechanisms should be put in place to make more use of these data sources – an effort in which both the medical defence organisations and other agencies such as the National Patient Safety Agency could play an important role

• Clinicians who are less experienced or in training should not be asked to work beyond their skills and abilities – simple lack of knowledge can result in serious errors – and should be able to decline responsibilities they do not feel able to shoulder

• Systems are needed for dealing with rare diseases or conditions that clinicians do not often encounter, keeping their skills and knowledge up to date and supporting their decision making on unfamiliar terrain.
1.1.2 How effective is training to help staff deal with obstetric emergencies?
Dr Bryony Strachan

Key Messages:

- Multi-professional drill training in obstetric emergencies improves knowledge and simulated clinical skills
- These improvements last at least one year and therefore staff working in maternity units should have annual drill training in obstetric emergencies
- High-tech, high quality simulation centres and low-quality local hospital settings are equally effective, but there are some advantages to training staff where they work – it is cheaper and offers the highest environmental quality
- Staff who lack competency initially in performing a procedure can be less motivated to attend training than more competent staff, therefore training should be mandatory for all staff
- High-tech and quality models are more effective in improving the procedural skills of healthcare professionals to deal with situations such as the birth complication shoulder dystocia
- All teams improved their teamwork scores after drills, but extra teamwork training did not confer any additional benefit on clinical skills. However, communication improved most in a team work trained group, so team work training should be incorporated into drill training, but not at the expense of clinical skills.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

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As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

It is believed that half of deaths of mothers and babies just before and after birth (perinatal) can be prevented with better clinical skills and team working. Obstetric claims represent one in five cases dealt with by the NHS Litigation Authority and 80% of the costs of all claims.

To tackle this, obstetric emergency management training, known as drill training, has been recommended for some time by national bodies and experts, but so far there has been no objective evaluation carried out into such training. Drill training can be used to teach staff to work together and communicate more effectively and helps staff be prepared for high-risk events, such as:
- Shoulder dystocia – a birth that requires additional obstetric manoeuvres to release the
baby’s shoulders
- Eclampsia – fitting with high blood pressure in pregnancy
- Maternal haemorrhage

**Aims of the Study:**
The study's main aim was to evaluate the effect of individual and team drill training for managing acute obstetric emergencies. Its specific objectives were to:
- evaluate different intensities and methods of obstetric emergency simulation training, measuring skills objectively
- explore the effect of ‘team training’
- evaluate objectively how much that learning had decayed six months, and one year after training.

**About the Study:**
The researchers wanted to compare training in a ‘low fidelity’ setting – training provided locally at department level – with a ‘high fidelity’ setting – using computer operated mannequins that respond to treatment in a dedicated simulation centre. They used several methods for their study which was organised in two phases.

The first phase was to develop evaluation methods and tools to study the effect of simulation centre and labour ward ‘fire drill’ training interventions for managing acute obstetric emergencies. The researchers developed interventional educational packages for the study and piloted the study design to ensure the trial on staff was feasible.

The second phase was an exploratory trial of education interventions on health care. It sought answers to the questions:
- Does the use of a high fidelity setting (simulation centre) and team training in emergency drills both improve clinical skills in obstetric emergencies?
- Does team training in emergency drills and the use of a high fidelity setting improve knowledge in obstetric emergencies?
- Does team training and the use of a high fidelity setting in obstetric emergency drills improve team working?

They also had staff take part in specific team work training.

**Practical findings:**
**Designing the training**
To develop the training intervention, the researchers designed a one-day obstetric emergencies course and a two-day course with the same clinical content as the first but with teamwork training included. Both courses were organised in modules with interactive lectures, drills and workshops for a defined syllabus of obstetric emergencies. The course manual was developed by the multi-professional team including local experts and every chapter was peer reviewed by local experts and the manual by three national experts. Participants were randomly allocated into multi-professional teams made up of one junior and one senior doctor with two junior and two senior midwives.

All the teams took part in a simulated emergency drill at the start of each session, followed by a PowerPoint presentation of the relevant lecture, after which they repeated the simulation. One team member was an observer, completing a clinical checklist which had key actions that should have been done during the simulation.

The high fidelity setting of the simulation centre used computerised mannequins and had regional trainers. The local low fidelity setting used the labour ward rooms, simple mannequins and local tutors. The second of the two-day training was focused on team work training on communication, roles and responsibilities and situational awareness.

Both types of course were tried out and piloted by 16 midwives and eight doctors each from
Derriford Hospital, Plymouth, and St Michael’s Hospital, Bristol. The pilots took place at the Bristol Simulation Centre (for the high-fidelity training) and at each participating hospital (low-fidelity training) with emergency drills conducted on labour wards.

**Assessment tools**

The researchers designed tools that would evaluate the effect of simulation centre and labour ward ‘fire drill’ training interventions for managing acute obstetric emergencies. These tools had to be able to measure doctors’ and midwives’ knowledge and skills for managing acute obstetric emergencies as well as their teamwork. Two pilots were carried out and these involved four obstetric emergency scenarios – shoulder dystocia, postpartum haemorrhage, eclampsia, and cord prolapse.

**Main study of training**

For the main study, there were 140 participants in 24 teams from six district general hospitals. Each team consisted of a junior and a senior doctor and two junior and two senior midwives.

Of those who entered the study, 132 completed the post-training simulation assessment. Six months later, 71% of the participants completed assessments and this fell to 63%, 12 months later. The researchers measured individual and team clinical skills by measuring the:

- number of key tasks involved
- time taken to carry out procedures
- number of actions, omissions and inappropriate actions
- applied delivery force in the drill for shoulder dystocia (a birth that requires additional obstetric manoeuvres to release the baby’s shoulders).

They measured knowledge by using a multiple-choice questionnaire testing facts on obstetric emergency topics and measured team working by using a global rating score for teamwork behaviour, communication, and a questionnaire. The measurements were taken before and immediately after the training and again at six and 12 months. Participants engaged in three simulated scenarios – shoulder dystocia; post-partum haemorrhage; and eclampsia and were recorded on film.

**Individual and team clinical skills**

During the drill for shoulder dystocia, the researchers noticed that individual clinical skills improved after training in all the groups of staff. The number of participants achieving a successful delivery increased from just 43% to 83% after training. Those people trained in the high-fidelity simulation setting had a higher chance of an advanced skill of removing the posterior arm but a lower likelihood of calling the paediatrician. There was no additional benefit of team training.

It also became evident that staff who had been able to deliver the baby before training were more likely to attend all four sessions (70%) organised for this study, compared with just 40% of those who had been unable to deliver the baby before training. This indicated that staff who lack competency initially can be less motivated to attend training.

During the drill for eclampsia, the average time taken to complete five basic tasks – including lowering the head rest, placing into recovery position and giving oxygen – improved after training from 55 seconds to 27 seconds. There was no difference, however, in the improvement after training between settings or with the addition of team training.

The number of errors or omissions made by the teams also fell from 39 before training to just 11 after training. During the drill for post partum haemorrhage, the average range of key actions increased slightly from eight to nine after training. This drill training also improved clinical skills in managing post partum haemorrhage shown by the time to complete key actions and global rating of team clinical skills. The researchers, however, found there was no significant effect of team training or high fidelity setting on improving clinical skills.

**Knowledge and team working**

Across all of the training groups, the researchers found there was a significant increase in individual knowledge by 20.6 points. Most – 123 out of 133 participants – improved their scores after training with good retention at 12 months. There was no added benefit of either fidelity or team work training.
Team work attitude questionnaire
The questionnaire given to staff showed that team training gave individuals a better insight into the effects of stress and better awareness of the safety climate but only in the low fidelity local setting.

Other attitudes to team working, job satisfaction and management’s role in safety were unchanged. More positive comments came from people who attended the simulation centres than those who attended local ‘in-house’ training, but the latter groups said it had improved their local knowledge and was an advantage in their work.

Summary of main findings:
- Knowledge of obstetric emergency management increased significantly after drill training for all the groups of staff who participated
- Staff’s knowledge after training was the same whether trained in a local setting or at the simulation centre
- Team work training did not affect knowledge scores
- The number of health professionals who achieved a successful delivery of a baby during a complicated birth simulation almost doubled from 43% to 83% after training
- Staff completed five basic tasks during a drill for eclampsia in almost half the time after they had received training
- Errors and omissions made by teams of clinicians during an eclampsia drill fell from 39 to 11 after training
- The training courses in both high-fidelity and low-fidelity settings were very popular with the staff and trainers who participated – 98% of participants said lectures were relevant and the scenarios were helpful.

Conclusions, recommendations and implications for practice and policy:
- Multi-professional drill training in obstetric emergencies is worthwhile in improving staff’s knowledge and skills
- Future research should explore whether these improvements in simulated performance can improve real life outcomes for mothers and their babies
- Using high-fidelity simulation centres for emergency obstetric training shows no advantage over using a local setting
- A descriptive study that compares simulation versus real life in obstetric skills training might be worthy of consideration
- Studies are needed to explore which aspects of team working are most relevant to obstetrics and how to teach these
- The role of simulation centres in obstetrics needs to be evaluated further for training trainers, sharing good practice between hospitals and providing a research environment for training interventions.
1.1.3 Failures in childbirth care

Key Messages:
- Staff are reluctant to carry out an unplanned caesarean section once labour has begun and take too long before deciding to intervene in this way.
- Not all adverse events are recorded in hospital trusts’ critical incident reporting scheme but should be.
- There is a worrying lack of knowledge underpinning practice especially relating to the signs of obstruction during labour due to cephalopelvic disproportion (when the baby is too large to fit through the pelvis).
- Staff inexperience and lack of adequate supervision and guidance is involved in almost all cases of adverse events in childbirth.
- The culture of the labour ward means less experienced members of staff are expected to get on with the job and do not seek help even when they are unsure of what to do.
- Staff have become too casual about the use of Syntocinon (drug to help induce and continue labour) and underestimate the risks of using it.
- There is a need for technical training on a time-out basis for midwives and obstetricians so they can accurately interpret technical equipment recordings during births.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

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As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Obstetric claims account for half of all NHS litigation bills with the average cost of cerebral palsy cases being around £1.5million.

Aims of the Study:
The aims of the project were to identify the underlying root causes of 37 cases of adverse events or near misses in obstetrics, using a systems approach rather than a person approach.
About the Study:
The researcher studied 37 cases selected from seven maternity units within the north west of England. The units studied covered a range of available facilities, including three large inner-city units with a high number of deliveries and significant obstetrical complications. Four of the seven units practiced a team midwifery system in line with that recommended by the government in its Changing Childbirth guidance and most of the midwives there worked on a labour ward for a day at a time. Their experience, therefore, was infrequent and patchy.

The other three units adopted the traditional approach of using block allocations to the labour ward which meant the midwives there had more consolidated experience.

The researchers interviewed 93 members of staff altogether, of which 81 were midwives, two were consultants, 8 were registrars, one was a senior SHO (senior house officer) who had been acting in the role of registrar, and one was a junior SHO. A panel of expert witnesses was used to identify the areas of mismanagement in each case and these were analysed.

Practical findings:
For this work, the researchers used findings from an earlier study by the author to provide background information about latent failures within the system of care on the labour ward. In the 37 cases studied, all involved a child with severe birth asphyxia – where the child had problems receiving enough oxygen before, during or just after the birth process – and these children were taken to a neonatal unit. Many were considered to have a poor prognosis. Staff were interviewed to supplement information gathered from case records and recordings from cardiotocography (CTG) – the technical means of recording fetal heartbeat and contractions during childbirth.

An ‘expert’ assessment board then identified areas of mismanagement in each case when it was clear from the interviews that different acts or omissions should have happened. This team included two consultant obstetricians, a consultant midwife, a midwifery risk manager, a consultant neonatologist, a neonatal midwife, and the researcher. A root case analysis then took place, using accepted methods.

Of the 37 cases, 32 were adverse events and five were near misses, but all involved inappropriate action, a failure to take action or a delay in taking action. The researchers found that overall, at least 15 infants were likely to develop cerebral palsy due to a poor prognosis and all the cases were often complicated. Less than half of the cases (16) were reported in trust’s incident reporting schemes, meaning 21 went unreported because either:

- there was a lack of recognition that an adverse event had just happened (some saw it as a near miss)
- or the case was not considered to be serious enough
- or midwives felt the consultant had acted inappropriately and contributed to the cause of the event, but did not want to openly criticize him.

The largest amount of adverse events (20 out of 37) happened during a night shift.

Type of failures
Although human error was associated with every case looked at, this was linked to many factors such as a lack of clinical experience, lack of labour ward skills and knowledge, lack of training and lack of supervision of inexperienced members of staff. In all cases, there were failures to identify obstetric complications and either a failure to act appropriately, a delay in doing so, or else inappropriate action was taken due to the above reasons. Various types of human failures happened including:

- not taking appropriate action at signs of fetal hypoxia (distress)
- the fetus not being monitored adequately
- not recognising an obstruction during labour
- using Syntocinon – a drug given to help induce or continue labour – inappropriately
- failing to provide adequate supervision, support and guidance for junior and inexperienced staff
- delays in providing adequate resuscitation for a newborn baby having breathing difficulties.
From the 37 cases, there were 13 emergency caesarian sections, two deliveries by forceps, 10 by ventouse and 12 normal deliveries.

**System failures**
The researchers found there were 34 cases in which there were no guidelines or protocols to advise regarding clinical practice or organisational issues.

**Unsupported junior staff/inexperienced staff**
The seniority and experience of staff in these cases was also noted by the researchers as an issue. In more than half of the cases (19) the lead midwife providing care was either junior or inexperienced and many said they felt less confident in their labour ward skills.

In nine of the 15 cases of babies with the poorest prognosis, the main caregiver was a junior or inexperienced midwife. Similarly with medical staff, in 31 cases, problems arose due to the use of unsupervised junior medical staff who were in the first ‘on-call’ position for complications. In eight of the 15 cases involving infants with the poorest prognosis, the obstetricians involved were inexperienced. This problem became clearer when in 19 of the 37 cases, a paediatric registrar had to be ‘crash called’ quickly to help. This was due to a lack of sufficient skill and experience to resuscitate the infants adequately.

**Communication and cultural issues**
Failures in communication were a problem in all the cases studied by the researchers, and were often related to culture on the labour ward – a system that is hierarchically led and historically based. When midwives and obstetricians had differences of opinion, they often failed to seek senior assistance because they feared it would damage their working relationship with registrars.

There were failures to provide assistance to junior or inexperienced members of staff, and a failure for them to seek it when needed (29 cases). The culture of the labour ward seems to mean less experienced members of staff are expected to get on with the job and not seek help even when they want or need it because they feared it would damage their working relationship with registrars.

In 31 cases, problems arose when junior or inexperienced medical staff members were used in a ‘first on-call’ position for complications, also a cultural issue. In 19 cases involving delayed infant resuscitation, the paediatric senior house officer (SHO) attended unsupervised, and the registrar had to be called in an emergency to assist. In 15 cases there was a difference of opinion between midwives and obstetricians regarding how and when to act, but no mechanism in place to support resolution.

**Heavy workloads and reduced midwifery staffing levels**
Workload was identified as an important factor and the researchers found that in 26 out of 37 cases, the adverse event or near miss happened during a very busy time on the labour ward when there were not enough midwives to manage cases safely. In 10 of these 26 cases, there was a reduction of at least one midwife from the established number required on duty and in 10 other cases a poor skill mix (too many junior midwives) put additional pressure on the already heavy workload.

The researchers found in 19 cases there was inappropriate use of high-risk procedures, involving the use of Syntocinon – a drug given to help induce or continue labour – and epidural blockades during busy times on the wards. There were also no guidelines or protocols to highlight the risks and special precautions with using Syntocinon.

In nine cases, there were high-risk or elective procedures (such as induction of labour and planned caesarean sections) used with inadequate midwifery staffing levels. All of these were evidence of latent errors in the system, said the researcher, creating an environment in which accidents were waiting to happen. There were also problems related to changeover of medical and midwifery staff in seven cases.

Seven cases involved midwives taking time away from clinical duties to perform other duties including clerical duties, domestic duties when other support was unavailable, and porter’s duties,
transferring clients to the wards following delivery.

**Training needs**

Training needs were apparent from interviewing the staff for the research. In more than half of cases (21), midwives and obstetricians lacked consistent updating in cardiotocography (CTG) interpretation, with midwives often lacking opportunities to do so because of workload, with no opportunities for time-out training. In 18 cases, members of staff were unfamiliar with labour ward protocols and failed to follow them while in 11 cases, there were inadequate labour ward induction programmes for new members of staff. In 17 cases, paediatricians (mainly SHOs) appeared to lack training in infant resuscitation.

**Lack of equipment and equipment failure**

Equipment problems also played a part and in 14 cases there was a lack of, or a failure of equipment, i.e. infant resuscitation apparatus and fetal blood sampling analysis machines. Only one of the labour wards in the maternity units studied had resuscitation apparatus in every room where deliveries might happen.

**Summary of main findings:**

- Of 37 cases studied, at least 15 of the children had a poor prognosis and were likely to go on to develop cerebral palsy

- More than half (56%) of adverse event cases were not reported to the trust's critical incident reporting scheme

- Three quarters of cases of adverse events happened in intensely busy periods with inadequate numbers of midwives and most (20 out of 37) happened during night shifts

- In almost all the cases (32) there were inexperienced midwives and obstetricians lacking labour ward skills, who were left unsupported and unsupervised with complicated cases

- In three quarters of cases, junior or inexperienced members of staff failed to seek help they needed because the culture of the labour ward discouraged them from doing so

- In a third of cases there was a failure to recognize cephalopelvic disproportion (when the baby is too large to fit through the pelvis) as an underlying cause of failure to progress in labour

- In almost half all cases there was an excessive or inappropriate use of Syntocinon (drug to help induce and continue labour)

- Inexperienced and unsupported clinicians who lack the necessary skills in infant resuscitation are often present at deliveries of babies with breathing difficulties at greatest risk of developing cerebral palsy.

**Conclusions, recommendations and implications for practice and policy:**

- Midwives returning to work in the labour ward after a prolonged period need help and support from more experienced midwives because their knowledge, skills and confidence will have lessened while they were away

- Mandatory multidisciplinary training for cardiotocography (CTG) interpretation and managing life threatening complications such as shoulder dystocia should be provided on a time-out basis

- Consultants should be seen as a part of the labour ward team and not only as an advisor so they need to maintain their clinical skills in this environment
• The profile of cephalopelvic disproportion as an underlying cause of failure to progress in labour, Syntocinon, and labour complications should be raised amongst staff to increase their knowledge

• Adverse events reports should be completed for all infants admitted to the neonatal unit

• Efforts should be made to change the existing hierarchical culture in the labour ward by encouraging more goodwill, cooperation and team work between different professional groups

• Members of the medical team need to provide junior and more inexperienced practitioners with more supervision and support

• Trusts need to set realistic minimum midwifery staffing levels for labour wards as this is a high risk area prone to significant medical accidents and high financial litigation.
1.1.4 Disordered brain function in newborn babies – trying to measure the scale of the problem
Dr Jennifer Kurinczuk

Key Messages:
• There is no universally agreed and accepted definition of neonatal encephalopathy (disordered brain function in newborns) in general clinical, or research use
• A universally agreed definition of neonatal encephalopathy which does not presume causes and which can be applied easily, is urgently needed
• Unclear definitions mean it is difficult to measure and monitor how often neonatal encephalopathy happens, investigate its causes and prevent it from happening
• Research is needed to look at the causes of neonatal encephalopathy and what role care during pregnancy and delivery play
• A specific term spelling out exactly what neonatal encephalopathy is would help clinicians and researchers
• All interested parties should help to build a consensus of opinion about what a good definition of neonatal encephalopathy is so it can be adopted by the relevant health professionals.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
• explore the size and nature of the problem
• understand the factors causing harm
• develop interventions to reduce errors
• assess how effective have the attempts to reduce errors been
• implement ways of guaranteeing change in people and organisations.

Neonatal encephalopathy - disordered brain function - in newborn babies is a condition of impaired neurological function. It is characterized by difficulty in initiating breathing at birth and keeping breathing, depression of tone and reflexes, abnormal levels of consciousness, and fits. In 2000, brain damage to babies at the time of birth was estimated to cost the NHS an average of £1.5million rising to £4m in litigation cases every year. The government set a 25% reduction target in the number of instances of negligent harm in obstetrics and gynaecology that lead to litigation by 2005.
Aims of the Study:
The aims of the project were to:

- review existing research to explore the issue of definition surrounding the diagnosis of neonatal encephalopathy and its severity
- estimate the trends in the incidence of neonatal encephalopathy and stillbirths during labour and delivery over the last decade in the UK
- explore existing research and data to identify the contribution of labour and delivery to the problem and identify potentially preventable mechanisms to the causes of neonatal encephalopathy
- make recommendations about future monitoring and research, particularly the value of neonatal encephalopathy as a measure of potentially preventable labour and delivery events
- provide sufficient information to be able to calculate the size of studies needed in the future to investigate this problem further.

About the Study:
The researchers carried out an extensive search of relevant existing studies published between 1966 and 2004 to find definitions of neonatal encephalopathy used in other research. They then carried out a process to reach a consensus of opinion about the definition to be able to monitor this condition in the future. This involved consulting a group of experts, discussing agreed definitions with a larger group of experts and interested parties, and producing an agreed definition document.

They also studied existing research to see whether the number of cases of neonatal encephalopathy have been rising or falling in recent years and whether adverse events during labour and delivery played a part in the problem.

Practical findings:

**Literature review**
The researchers carried out a search of relevant existing studies published over a 38-year period to find publications that either discussed and defined neonatal encephalopathy or carried out studies that used a definition of it. They identified 12 key publications that were suitable. Following this, they decided to come up with a consensus approach to fixing a definition of the condition for general use in healthcare and for monitoring (surveillance) of the problem. To do this, they consulted experts to come up with a series of relevant definitions, which were discussed, tested and agreed. That process was still happening at the time this paper was published.

Historically, neonatal encephalopathy has been defined in a way that suggests that its causes are known in every case and often originate during the labour and delivery of a baby. The researchers said this was almost certainly not an accurate picture of its causes in every case. They found from existing research that because of the lack of a universally accepted definition for neonatal encephalopathy that does not presume causes, coming up with a full description of the risk factors for the condition has been difficult. An unclear definition meant it was all the harder to measure and monitor how often neonatal encephalopathy happens, to investigate what caused it and try to prevent it from happening.

The researchers said that despite the efforts of leading researchers in this field to discourage obstetricians and neonatologists from using certain terms such as birth asphyxia, perinatal asphyxia and hypoxic-ischaemic encephalopathy (a severe complication of suffocation that happens before, during, or after birth), they were still used commonly. This practice should stop, they said, when talking about neonatal encephalopathy because such terms were inappropriate and often unhelpfully used.

**Trends and how often neonatal encephalopathy happens**
Only two existing studies considered by the researchers gave an accurate estimate of the incidence of neonatal encephalopathy. They also considered two regional population-based data collection systems to examine the neonatal encephalopathy rate over the last decade as well as hospital-based data collection systems.
They found that over the 12-year period of 1991 to 2002, there were 704,130 live births in one geographical region of the UK and of those, 808 infants were admitted to neonatal units with hypoxic-ischaemic encephalopathy (a severe complication of suffocation that happens before, during, or after birth). This was an overall rate of 1.2 per 1,000 total live births. There was no evidence of a decline in this condition over the most recent six years of this period (1997 to 2002).

In the other regional population-based data, there were 247,480 live births, of which 450 infants were defined as meeting the encephalopathic criteria. This was an overall rate of 1.8 per 1,000 total live births. From both regions, the researchers concluded that there was no evidence of a decline in the rate of encephalopathy over time. There was also no evidence of a decline in the rate of severe cases over the periods studied.

**Stillbirths**

The rate of stillbirths where the baby died during labour or delivery in the two regions looked at did not change significantly over the period measured. From 1996 to 2001 – the period during which similar data were available for both regions – the rate of stillbirths during labour or delivery was 0.3 per 1,000 total live births in one region and 0.3 per 1,000 in the other region, including deaths with an uncertain timing.

There was no evidence of a change in the stillbirth rate from the mid-1990s onwards and the researchers were not able to make any link between stillbirths and what effect that may or may not have had on the neonatal encephalopathy rate nationally. The researchers concluded that it was not possible to have an accurate estimate of the national rate of neonatal encephalopathy because of the absence of an agreed definition. Statistics are limited and different regions may be counting different things as cases of neonatal encephalopathy. Because of the way the information is collected, there is a possibility of under-counting of cases.

They were more confident to say that there has not been a notable decline in the rate of hypoxic-ischaemic encephalopathy (a severe complication of suffocation that happens before, during, or after birth) and encephalopathy since the mid-1990s. Data they considered showed that both younger (under 20) and older (above 30) mothers were at an increased risk of having a brain damaged infant at birth.

**Labour and delivery – its impact on neonatal encephalopathy**

The researchers looked at existing research to see if adverse events during women’s labour and fetal distress contributed to neonatal encephalopathy. They found four suitable studies to consider but these had a wide variety of purpose, design and were conducted in different ways as well as using different assessments of how the labour process contributed to problems. Such limitations meant that the researchers could not use the data to confidently estimate what role adverse events during labour and the care provided during labour played in causing neonatal encephalopathy.

**Summary of main findings:**

- Universal definitions of neonatal encephalopathy do not exist but are needed to allow the NHS to measure how often it happens, why and come up with ways to prevent it.

- It is not possible to give accurate figures for the rate of neonatal encephalopathy in the UK because of the lack of a clear and universally agreed definition.

- Nevertheless, available information suggests the rate of neonatal encephalopathy amongst new born infants does not seem to have declined in recent years so the problem is not being solved.

- Clear estimates of the contribution of adverse events during women’s labour and fetal distress to causing neonatal encephalopathy are not possible because of different definitions used and different criteria used in various studies.

- It may not be possible to collect the necessary level of detail required by current criteria to
identify what contribution adverse events during labour/delivery and fetal distress make in every neonatal unit in the UK.

Conclusions, recommendations and implications for practice and policy:

- The best way to reach a universally agreed definition for neonatal encephalopathy is to adopt a consensus approach talking to experts and all interested parties

- Using an agreed definition of neonatal encephalopathy when collecting data would allow national surveillance of this condition

- Success in defining neonatal encephalopathy in the future will be more secure if terminology is endorsed by organisations such as the British Association of Perinatal Medicine, the Healthcare Commission, and the Department of Health

- Urgent research is needed to look into the causes of neonatal encephalopathy and what role does care during pregnancy and delivery play in causing it

- It might be necessary to consider collecting information from a limited number of neonatal units in the UK identified either randomly on a rolling basis or from neonatal networks to help build useful criteria to judge what part adverse events play during labour/delivery towards causing neonatal encephalopathy

- The use of certain terms by clinicians such as birth asphyxia, perinatal asphyxia and hypoxic-ischaemic encephalopathy (a severe complication of suffocation that happens before, during, or after birth) should be dropped when talking about neonatal encephalopathy because they are often inappropriately and unhelpfully applied.
Chapter 2 – Response to Patient Safety Initiatives

2.1 Introduction by

Professor Richard Thomson
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&

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This collection demonstrates the wide diversity and breadth of coverage of the work commissioned by the PSRP during its funded period. There is much here that the National Institute for Health Research can learn as it continues to fund relevant patient safety research through its remaining programmes.

The projects in this chapter are concerned with evaluating the response to safety initiatives, and cover patient safety issues ranging from NPSA alerts on topics such as correct site surgery and concentrated potassium chloride, through to the value of standardised root cause analysis training. Yet within this diversity common themes are apparent.

Several projects demonstrate the age old problem of failure to develop or implement guidance, from not using, or only partly following, the NPSA’s correct site surgery alert, to 14/23 departments in one hospital not following hospital policy on how to use wristbands.

An external observer of these findings might be forgiven for asking what is going on. Why can’t the NHS implement these simple changes for good and safer practice? The answer is, of course, that it is not always that simple; there are findings within the reports that reinforce what we know in the wider literature about the challenge of implementing change and complex interventions. Thus, the importance of clinical engagement (or not) is apparent in the apparently patchy implementation of the correct site surgery alert, with some departments demonstrating “universal refusal to comply with the alert’s requirement to mark all patients before surgery”. This arguably small minded assertion of autonomy is disturbing but, as the report shows, may have valid (if not entirely defensible) reasons. The clinicians’ arguments against the guidance seemed largely to relate to concerns about safety of this new advice itself, such as continuing to wrong site mark.

On the other hand, the alert about removing concentrated potassium chloride from general wards seems to have been well implemented, begging questions as to why that might be so. Perhaps the clearest answer lies in the response that managers felt the changes were “relatively straightforward to implement”. In terms of implementation other key factors emerge from these reports including the value of leadership (for example the seniority/authority of those responsible for receiving and responding to alerts), clarity of message (shown by confusion around re-use of medical devices or suggestions for grading of risk in alerts), appropriate targeting to the audience responsible for change (57% of general practices thinking alerts were mostly irrelevant to them), the importance of good communication, local (clinical) engagement (the value of this in implementing correct site surgery), and context and local audit/review (32% of trusts had not audited the implementation of alerts).

What emerges from a reading of these reports is that, whilst much has been achieved, barriers to implementation and change remain that limit the capacity to make the NHS as safe as it might be. As argued in the document Safety First, local leadership and culture change is required. There remains a need for research into factors that facilitate or hinder change locally, and a greater focus within implementation strategies on what we know from research is likely to work.

2.1.1 Safety alerts on drugs – how trusts follow the rules
Professor Trevor Sheldon

Key Messages:
- Trusts are willing to follow guidance of this type issued by the NPSA and took it seriously, acting quickly on its instructions
- Before this alert, many trusts had taken action to alert staff and raise awareness of the potential dangers of this drug, but the scope and success of this action was variable
- Many staff felt the timescale for implementing the NPSA alert was too short
- Trusts should develop a coherent strategy for the handling of future NPSA guidance
- There is a need for ongoing audit of the storage and use of potassium chloride concentrate because there are several factors suggesting strong potassium chloride ampoules may gradually return to unauthorised clinical areas over time.
- Junior doctors had a worrying lack of awareness over the storage and handling of drugs or how to obtain them out-of-hours, some saying that it was not their concern and was entirely down to nurses.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Errors in medication are estimated to make up one quarter of all adverse incidents. Potassium chloride is the drug of choice to prevent or correct hypokalaemia, which happens where there are low potassium levels in the blood and leads to muscle weakness, heart irregularities, disorientation, and sometimes cardiac arrest. A patient with severe hypokalaemia is at risk of sudden death from respiratory or cardiac arrest. The drug, however, is extremely toxic in high concentrations and has been produced in ampoules that look very like others containing sodium chloride and water for injection. Cases of staff mixing up these ampoules have led to some patient deaths and near misses.

Aims of the Study:
The researchers set out to evaluate how well trusts responded to a safety alert issued on concentrated potassium chloride and determine the nature of any expected or unintended consequences. Its specific aims included:
- to determine the degree of existing concern and consequent action taken in advance of the directive
• to carry out an audit trail of action taken in the wake of the directive
• to describe the variety of recording methods adopted for the supply, storage and administration of concentrated potassium chloride
• to determine the effectiveness of the action taken to implement the directive
• to explore the difficulties created by compliance and identify successful strategies adopted
• to record changes (if any) to the out-of-hours service provided by pharmacies
• to identify possible unintended consequences to inform future monitoring
• to record trust intent regarding ongoing monitoring and audit.

About the Study:
The researchers carried out an audit from a random sample of 20 NHS hospital trusts. During audit visits, interview schedules were held at each trust with senior managers and ward staff, while relevant policy documents were studied, and clinical areas were physically inspected to look for the presence of concentrated potassium chloride solution. The audit team also carried out an audit of the management of the NPSA guidance from the point of it being received at the trust.

Practical findings:
The study is based on a decision by the National Patient Safety Agency (NPSA) to issue an alert in 2002 to trusts saying that the concentrated solution of potassium chloride should:
• be withdrawn from clinical areas other than intensive care environments
• be prescribed in commercially available concentrations
• be diluted in pharmacies when no commercial product of the correct concentration is available
• be subject to the same recording processes as controlled drugs
• be stored in a locked cupboard
• be signed for by a second practitioner
• not be transferred between clinical areas

The researchers said that implementation of such directives from the likes of the NPSA meant a change in behaviour for pharmacists, doctors and nurses which was not straightforward. They wanted to audit the extent to which trusts complied with the alert.

Senior managers
The senior managers seen during the audit visit interviews were clinical governance leads, chief pharmacists, directors of nursing, and clinical risk managers. In all, 70 managers and pharmacists were interviewed individually or in small groups of 2-4 people.

Ward managers and junior doctors
An average sample of eight ward managers and two junior doctors were interviewed at most trusts to see what their awareness of the NPSA directive was and explore any problems that had come up as a result of it. In all, 217 people in this category were interviewed and included house officers, senior house officers, specialist registrars, ward sisters, staff nurses, consultants, matrons, agency staff and nurses in charge of the area at night.

Audit of clinical areas
In each trust, a minimum of 10 wards or departments were audited using a ward audit document. The process involved the auditor inspecting cupboards containing controlled drugs, oral drugs and intravenous (IV) drugs. They also looked at other storage facilities in the vicinity such as the drugs trolley, cardiac arrest trolley, and in which drugs were kept.

Surfaces and cupboards in treatment rooms were also scrutinised as well as the storage area for IV solutions. They also looked in boxes and containers holding sterile water and sodium chloride for injection and inspected the surfaces on which the injection solutions were prepared.
Analysis of documents
The researchers also looked at how the trust managed the action designed to follow the requirements of the NPSA alert. They asked for e-mails, minutes of meetings, copies of memos, and any other relevant evidence of consultation and action. They asked each trust for a copy of the policy or protocol developed in response to the NPSA alert and details of suppliers of dilute potassium chloride solutions. The information, however, provided by 18 of the 20 trusts was of highly variable quality so the researchers did not analyse it.

Ensuring widespread knowledge of the alert
Word of the NPSA alert was spread quickly, the researchers found. Of the 20 pharmacists at the trusts studied, 17 had received the alert days, if not hours, after its publication. Many had been alerted to its arrival and requirements by their medical director who had received notification four days earlier, and most had also been alerted by regional pharmacy groups. In one trust, the chief pharmacist had received the alert but neither the medical director nor the director of nursing were aware of its existence until three months after its publication.

Previous action taken
The action taken when the alert was received varied from trust to trust. Most (95%) of them took some prior action to warn staff of the dangers of the potassium chloride concentrate and to reduce dependence on it, but the scope and success of this action was variable.

Some trusts were already treating it as a controlled drug, while others distributed memos by pharmacies to remind staff of the dangers of the substance and recommending the use of a wide range of available dilute solutions. Other action taken included:
- Storing it in a locked cupboard
- Removing it from all but critical areas
- Requiring two signatures before use
- Ongoing staff education.

When asked about concerns over the issue in the past few years, 55% of senior managers said there had been either high or medium concerns expressed within their trust. Nine of the trusts said action had been taken as a result of previous adverse events at the trust including death of a patient, injury to a patient resulting in severe disability and suicide and homicide by a member of staff using potassium chloride they obtained from the trust.

Managing the alert
Most trusts (70%) interviewed said the chief pharmacist was chosen to lead implementation of the NPSA alert, while the rest mentioned other staff members including chief executives, medical directors, and clinical governance managers. The majority of trusts praised their ‘proactive’ pharmacy departments and were very satisfied with the action taken, while pharmacists praised their medical and nursing colleagues for their support.

The timescale given to implement the NPSA alert was felt to be too short, given the need to consult with medical and nursing staff in areas where the concentrated solution was to be removed and given the committee structures at trusts. Four trusts either missed the deadline for implementation or had implemented the requirements in advance of final approval of their policy being agreed.

Knowledge of the alert and related changes to trust policy was high among staff, the researchers found, with 152 people out of 217 saying ‘yes’ they were aware of it, 53 saying ‘partially’ and just six saying ‘no’. The most effective way of communicating with ward managers was by circulating a policy or memo and via verbal information from the ward pharmacist. Other forms of communication included e-mail and routine meetings.

Managers generally felt the changes had been relatively straightforward to implement but said it was difficult to communicate those with all staff, especially in large trusts with many sites. There were several factors identified that had hindered implementation of the alert including:
- sheer weight of information descending on trusts every day
- large trusts found it hard to get information out across several sites
- recent mergers between trusts complicated matters
- cost consequences of replacing the ampoules
lack of ward storage space
• double checking and signing for the drug was time consuming
• some staff in areas such as paediatrics and haematology wards opposed removal of the concentrate.

More than half (53%) of managers questioned said they intended to audit compliance with the NPSA guidance, 26% did not know and 21% said they did not intend to.

Meeting the NPSA alert requirements
The researchers visited 207 wards, approximately half of which were authorised and half not authorised to stock strong potassium chloride solution. They found that 87 areas out of the 207 visited had concentrated potassium chloride present, of which only five were not named by the trust as authorised to have it, showing the policy had not been followed completely accurately.

They also felt that 18 authorised wards were found not to comply with a strict interpretation of the NPSA definition. Different trusts had different policies regarding out-of-hours arrangements. Five trusts, for example, said there could be no transfer of strong potassium chloride between ward areas without the approval of the pharmacist on call. When procedures were published, they were complex.

Almost all of the junior doctors interviewed were unaware of any procedures relating to storage and handling of drugs or obtaining them out-of-hours, saying that these were nursing responsibilities.

Unintended consequences
When asked about concerns over any unintended consequences of implementing the NPSA guidance, 20 senior managers said they did have some. Five said there was a need to monitor the possibility that restrictions could impede access to potassium chloride for patients who needed it.

Two managers were concerned about the UK evidence base for the NPSA alert and that its requirements had not been piloted first, while concern was also expressed at the potential de-skilling of staff in areas not authorized to keep the concentrate.

Interviews with ward managers showed that in most intensive care areas –where the drugs are used frequently – there was some unease about the NPSA requirements because of the time required to check and sign out the drugs and staff were spending more time on the process of getting these drugs rather than on direct patient care.

Summary of main findings:
• Nineteen trusts (95%) took some action in advance of the guidance being issued and all the trusts distributed policies and procedures in the wake of guidance
• Half of trusts had included storage and handling of strong potassium chloride in their training strategies ahead of rules saying they must and the same had included it in induction training for new staff
• An average of 78% of nurses and 30% of doctors were aware of the alert in the 20 trusts
• Trusts increased their stock of potassium-containing solutions since the alert was published
• Despite trusts taking action to restrict stocks of potassium chloride concentrate in clinical areas, unauthorised stocks were found in five clinical areas in three trusts that were not authorised by the trust
• Most areas in hospitals had inadequate storage space for controlled drugs meaning many different drugs were packed in small spaces piled on top of each other
• Labeling of strong potassium chloride was considered by staff to be too similar to other drugs and water for injection, creating real dangers from potential mix-ups.
Conclusions, recommendations and implications for practice and policy:

• Overall the NPSA guidance had been implemented in most trusts.

• Several factors suggest strong potassium chloride may gradually return to unauthorised clinical areas over time, including permitting the substance to be issued on a named-patient basis to unauthorised wards; cost; lack of storage space; inconsistent availability of some newer, stronger solutions; and difficulties in accessing concentrated potassium chloride out-of-hours.

• The timescale for implementation of future NPSA alerts should be sufficient to allow for progress of policies through trust committees.

• The NPSA should consider sending future alerts directly to particular health professional groups if they are going to act on them.

• One system should be adopted throughout the UK for strengths and labelling of electrolyte solutions.

• All trusts should develop specific protocols for access to strong potassium chloride out-of-hours.

• Packaging of strong potassium chloride should still be addressed despite the precautions put in place by the NPSA alert.
2.1.2 Reusing medical devices against the rules
Professor Robert Dingwall

Key Messages:
- Reuse of single-use devices still happens in the NHS in direct defiance of official guidance and although it is not widespread, it is still an important issue of considerable concern
- Reusing devices does not always save money and can actually cost the NHS more in the long run because of the adverse incidents this practice can cause
- There is a widespread lack of awareness about single-use devices
- Reusing single-use devices adds to the danger of patient safety through cross infection, contamination and device malfunction
- There is a perception that single-use devices are cheaper and inferior in quality than reusable ones
- Official guidance can be contradictory and confusing for clinicians
- Slight differences between manufacturers and the MHRA’s understanding of the definition of a single-use device can cause confusion and potential patient harm.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report, An Organisation with a Memory, by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

The NHS introduced the use of single-use medical devices following awareness that protein and bacteria remained on instruments following decontamination and sterilisation processes. Reuse of medical devices intended to be used only once poses a threat to patient safety from cross infection from prions, linked to BSE and CJD, found in the tonsils, appendix and brain, and from blood borne diseases such as HIV and Hepatitis B and C, as well as from device malfunction and breakage because of being reused. It was known, at the time this research was carried out, that re-use of such devices continues, despite guidelines and policies, such as those provided by the Medicines and Healthcare products Regulatory Agency.

Aims of the Study:
The study’s aims were to estimate the extent of reuse of single-use devices in the NHS by coming up with an inventory of single-use devices reported as being reused. It also had the objectives of carrying out a survey to investigate current practice and to do an in-depth study by interviewing clinicians to try and ascertain the reasons why staff do and do not reuse devices that are meant to be used only once.
About the Study:
The researchers work, carried out over a two-year period, was to study and analyse data that came from three sources:

- almost 500 published accounts of reused single-use devices from three continents
- a web-based survey of clinical staff working in operating theatres and anaesthetic departments in NHS acute hospitals in England
- in-depth interviews with 23 frontline NHS staff from 10 hospitals.

The researchers then analysed the single-use devices that were most often reported as being reused.

Practical findings:

Studying published accounts

Data for an inventory was gathered from published accounts of the reuse of single-use devices from scientific literature and came from the UK, European Union (EU), North America and Australasia. The researchers found 291 cases of single-use devices reported as having been reused and these included catheters, needles, laparoscopic instruments, breathing filters and biopsy forceps.

The researchers found that most cases (267) of reused single-use devices happened in the USA and Canada, but reprocessing of these devices is allowed in both countries.

In Europe, despite EU directives being in place, reports from the data suggest reuse of single-use devices was still happening. In the UK, there were 20 reports of reuse although the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) says that reuse should not happen under any circumstances. In Germany, there were 37 reports of reuse but it allows reprocessing as long as there is evidence of the device’s safety before it is reused.

Web-based survey

For this part of the study, the researchers wanted to focus on reuse of single-use devices in the English NHS setting, particularly in hospital operating and anaesthetic departments. The original systematic sampling strategy designed by the research team was obstructed by NHS research governance regulations, and a less satisfactory strategy for recruiting participants had to be used. This involved seeking the views of volunteers from relevant professional associations. A web-based survey was carried out involving a questionnaire with 16 questions looking at the types of device that may be reused and the specific contexts in which that might happen.

Definitions

The researchers found there was inconsistent understanding of what ‘single-use’ or the single-use logo meant in practice. They concluded that there was no agreed definition of a single-use device. They found a difference between the manufacturer’s clear definition of a single-use device – the device is designed to be used on a single occasion – and that given by the MHRA – which implied that single-use can mean single patient use during one procedure with ambiguity about it being reused during that episode of use.

This could cause confusion, warned the researchers, and a lack of consistency between the two definitions could result in patient harm. They mentioned anecdotal reports of cases of scalpel blades snapping and needles becoming blunt through extended use (albeit single-use) but the patterns of usage came within the MHRA’s definition of acceptable use – used on a single patient and not reprocessed. The MHRA’s definition has subsequently been altered to clear this problem up.

Devices reused

When asked, 62% of people responding said they had seen reuse of single-use devices, sometimes during every operation and sometimes more than once a week. Because no surgeons responded to the survey, the single-use devices reported most often as being reused were mostly found in anaesthesia. In all, 127 reports of reused single-use devices were received from 55 different hospitals and the device most often reused was the anaesthetic breathing system. It is known that anaesthetic breathing equipment shared between patients poses a risk of cross-contamination but it is sanctioned in the UK as long as the circuit is protected by a new breathing (bacterial/viral) filter for each patient, and with the breathing circuit being replaced every seven days.
The second most commonly reported device being reused was the facemask – used for oxygen therapy and anaesthetic facemasks – sometimes used in every operation or more than once a week. Both types of mask are intended for single-use only and they are known to pose a threat to cross-infection between patients. When asked why single-use devices were being reused, 50% of clinicians said it was due to the cost of replacing them after each procedure. Other reasons included:

- environmental impact of disposing of the clinical waste
- perceived lack of risk associated with reuse
- problems with the supply chain resulting in a lack of other equipment.

The researchers said that despite the cost implications, compromising patient safety by reusing a single-use device – by the risk of cross contamination or infection – meant a clinician was failing to meet their professional obligation to do no harm. There were other costs to consider, they said, such as medico-legal costs associated with cases claiming harm caused by unclean, unsterilised or contaminated surgical devices.

The researchers concluded that reuse of single-use devices was likely to occur because of:

- confusion about what single-use means
- a perceived lack of risk associated with reuse
- the lack of other available equipment
- the cost of replacing each device with a new one
- unrealistic expectations about disposal of certain devices after just one use.

**In-depth interviews with staff**

To put the survey findings more into context, the researchers carried out 23 in-depth interviews with frontline theatre staff from 10 acute NHS hospitals across England. Participants included theatre managers, operating department practitioners, sterilisation managers and clinical directors of anaesthesia. Questions asked of the people interviewed were designed to gather information about:

- why specific medical devices in specific settings were reused when they were not meant to be
- why they were not reused in some cases
- the cost differences between single-use and equivalent reusable devices
- the procedures used for decontamination and the associated costs when reuse had happened.

Most of the clinicians said their awareness of the risk of problems caused by physicians reusing devices was greater than it used to be, but they disagreed about how real or significant that threat was. In addition to the 127 cases of reuse reported in the web-based survey, the people interviewed mentioned 15 other cases of reuse they had observed at work. It became clear that clinicians were concerned about the threats to patients of exposure to cross contamination, but they were also aware that the risks might have been overestimated.

Discrepancies between guidance issued to surgeons and that issued to anaesthetists on certain medical devices were identified from the interviews, showing a lack of consistency between specialties that work in the same operating areas. The researchers found from the interviews there were many factors that led a clinician to reuse a single-use device including:

- the design and labelling of devices
- awareness and understanding of the single-use logo
- issues relating to the quality and effectiveness of single-use equipment
- contradictory official guidance
- human failings linked to knowledge and situational awareness.

The interviews also revealed that reuse was a cost-saving initiative as people were aware that the NHS had finite resources. People perceived that single-use devices were more expensive pro rata than reusable devices, but the researchers argued that the single-use devices were unlikely to be any more expensive when all factors were taken into account and could, in some cases, be a cheaper option. Some costs such as decontamination of a reusable device and possible repairs needed to damaged or broken equipment before reuse, ceased to be a factor when using single-use devices.
Although reusable devices appeared to present the cheapest option, said the researchers, the figures did not take into account the relative risks of infection, generating additional costs in compensation, additional treatment and extended in-patient stays, and the impact of missing or broken equipment on the continuity of theatre working.

Some clinicians were worried about the environmental impacts of using single-use devices – more packaging and equipment to be disposed of – but the majority considered this to be acceptable compared to reusing devices and thereby increasing the risk of infection caused by physicians and the threat to patient safety. The researchers argued for the risks to patient safety from the use of clean single-use devices to be balanced against the risks to patient safety by utilising single-use equipment that might not be fit for practice.

The staff responding were concerned that some single-use devices, produced at a cost and quality to warrant their disposal after one use, were comparatively unsafe, meaning that they preferred to use reprocessable devices, despite the risk from cross infection and contamination.

Summary of main findings:

- Almost two thirds (62%) of clinicians said they had seen inappropriate reuse of single-use devices where they work, sometimes during every operation they were a part of.
- Single-use devices are being reused in countries where such practice has been outlawed.
- Most clinicians justify reuse of single-use devices for financial savings.
- Reuse of single-use devices is likely to occur because of confusion about what single-use means, a perceived lack of risk associated with reuse and the perceived cost of replacing each device.
- Clinicians recognise that in the most part, using single-use devices is in the patient’s best interests but feel they do not always function as well as they want them to.
- The vast majority (91.8%) of reported cases where single-use devices are reused are in North America where this is permitted but not always regulated.
- Different staff have a different understanding of exactly what single-use device means.

Conclusions, recommendations and implications for practice and policy:

- Professional associations and Royal Colleges should work together to address inconsistencies in infection control guidelines regarding the use of some equipment.
- Labelling inconsistencies need to be addressed so that labelling on each device, packaging and paper insert (instructions) are consistent.
- Colour coding of devices to differentiate between single-use and reprocessable should be investigated.
- Attention should be given to harmonising the existing different definitions being used for single-use devices which currently can lead to confusion, followed by a high profile educational campaign targeting all stakeholders.
- A microbiological study of the risks relating to the reuse of masks could be worthwhile, looking at how realistic it is to expect anaesthetists to change masks after every procedure.
- Although it is likely that inappropriate reuse is more likely to happen in bigger hospitals, future research could look into regional variations in this practice of reusing.
• An awareness programme aimed at clinicians should be organised to tackle the perception held by some that single-use devices are cheaper and place patients at greater risk than a reprocessable device.

• NHS research governance acted as a barrier to the research, meaning that not all data collection could be undertaken. Given the changes now in place regarding ethical governance, the survey component of the research could be undertaken again, to gain more robust data.
2.1.3 Testing new devices to help prevent ‘connector’ errors in healthcare
Dr Rebecca Lawton

Key Messages:
- Some clinicians are enthusiastic about moving to non-Luer compatible equipment (Luer being the current norm used in patient care) but there may also be some resistance, particularly from anaesthetists
- Although clinicians are enthusiastic about the potential benefits to patient safety of introducing the new connector devices, several drawbacks in the current design were identified, such as translucency and the fiddly rotating collar
- Most clinicians would be happy to use the new non-Luer devices in routine care as an engineered solution to intrathecal ‘cross-connection’ errors, but only after minor yet crucial modifications are made to them
- Anaesthetists believe the new devices do not address significant problems in their area of practice such as wrong drug errors
- Before any changeover to using the non-Luer devices happens, there should be careful preparation in terms of training staff, involving them at all stages and a precise change date on which old equipment is systematically removed to avoid crossover confusion.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective the attempts to reduce errors have been
- implement ways of guaranteeing change in people and organisations.

Within patient care, Luer connection systems are the standard way of attaching the likes of syringes, catheters, hubbed needles, IV tubes to each other.

Problems, however, are well known with ‘cross-connection’ (misconnection) errors that happen when drugs meant for one route of administration are administered via an inappropriate route. These errors are made possible by extensive use of ‘Luer’ connectors for a variety of procedures and cross-connections can be fatal for the patient.

Spinal misconnection in oncology and anaesthesia is a significant problem. The Department of Health is keen to introduce a design solution to this problem so dedicated spinal connectors would prevent inappropriate devices being connected to spinal needles and infusion lines.
Aims of the Study:
The overall aim of the study was to investigate the potential for and implementation of non-Luer compatible equipment, i.e. non-traditional connector equipment to be used for spinal procedures. The study’s specific aims were to:
- gain knowledge of the scale and nature of the problem which the new devices were designed to overcome
- gain familiarity with the various devices currently in the prototype stage
- assess the potential problems associated with introducing new non-Luer devices.

About the Study:
The researchers carried out their study in three phases:
- A prospective hazard analysis which involved analysing existing data on adverse incidents to do with traditional Luer connection systems; performing a task analysis for oncology and anaesthetics, and using this as a basis for workshops with clinicians to analyse the potential hazards of using these new devices in practice
- Testing prototypes on a simulator to assess the usability of the new connector devices
- Trialing new devices in four NHS trusts to see how safe, effective and practical they were by involving clinicians using the devices to administer over 350 injections into the spinal canal. The implementation of the new devices and other organisational factors e.g. storage and pharmacy were also investigated at this stage.

Practical findings:
Reviewing the existing evidence
The researchers began their work (first phase) by studying what existing evidence and research was already around on this subject.

They concluded that the true incidence of spinal misconnection errors was hard to know precisely because of a lack of formal incident reporting in the NHS.

Case reports they considered indicated that this kind of error often happened as a result of a coincidence of a number of contributory factors relating to prescribing, dispensing, storage, delivery, labelling, supervision, fatigue, staff changeover, and equipment.

The researchers also observed relevant clinical procedures and carried out five interviews with clinicians – consultant haematologists and anaesthetists. This allowed them to gather data so they could compile a task analysis of the relevant procedures that formed the basis for the prospective hazard analysis to come.

Technical evaluation
Next, the researchers carried out a technical evaluation of the two proposed design options (prototypes) from an industrial design perspective. They wanted to investigate the compatibility of the prototypes with Luer connectors.

They concluded that both prototype devices could prevent a syringe being wrongly attached to a spinal needle.

The first prototype was found to be small and fiddly with a harsh grip area that made the connector uncomfortable to use. However, the researchers suggested that such a device should not be too large because when it was attached to a patient, a large one could be uncomfortable for them.

The second prototype was larger than the first with an ample-sized grip area, but part of it lacked adequate grip provision.

Both prototypes proposed using a colour coding system as way of identifying tubes and devices for different delivery routes to help hospital staff choose and use the correct connectors. This system was inadequate on its own, the researchers concluded, because of the variety of colour coding
systems used in the NHS, so they proposed an additional shape coding system to help staff identify devices correctly.

**Hazard analysis**
The next task was to carry out a prospective hazard analysis of the non-Luer spinal equipment. For this, the researchers held six hazard analysis workshops in which 24 healthcare professionals took part using the task analysis system designed by the researchers.

The participants included consultants, pharmacists, nurses, specialist registrars and technicians.

At these events, the clinicians were asked to consider the potential hazards relating to the use of the new non-Luer equipment for the relevant spinal procedures.

One workshop looked at intrathecal chemotherapy – one way of giving chemotherapy to treat certain types of cancer in which the patient gets chemotherapy via a needle that is put into their spinal canal.

The clinicians said using the new devices would not introduce any new hazards, but there were several shortcomings in the prototype solutions that would need to be addressed.

Before the new devices were introduced generally, the researchers said very few procedural changes would be necessary and the clinicians were very supportive and enthusiastic about moving to non-Luer compatible equipment.

Also the new equipment could, they said, lessen the chances of errors in intrathecal chemotherapy drug preparation and labelling.

From the workshops examining spinal anaesthesia, the anaesthetists felt there was a misplaced focus on spinal injections rather than on epidural and intrathecal infusions.

They felt that the proposed equipment would not provide a solution to wrong drug errors in this context, because of the way in which spinal anaesthesia is prepared. Consequently, the researchers said they anticipated some degree of clinical resistance to the introduction of non-Luer equipment in this area.

Overall, when asked about the acceptability of the new equipment, the healthcare professionals said the most significant drawbacks of the proposed connection systems were related to:

- visibility and how translucent or opaque the connectors were as this could cause difficulty in observing cerebrospinal fluid ‘flashback’ which shows the needle is in the right place
- the small diameter of the holes at the end of prototype syringes which caused problems in intrathecal chemotherapy preparation
- the need to twist the syringe in order to connect one of the prototype syringes to a spinal needle
- the relatively heavy weight of one of the prototype connectors
- the provision of one of the prototype devices in the form of a separable adaptor.

**Interviews with equipment organisers**
The researchers carried out several interviews with people who were responsible for getting hold of and the supply of new equipment for the NHS.

These individuals raised concerns about the initial lack of competition in the market resulting in equipment that would be too costly.

There were also concerns over the growth of new non-Luer devices if a more general standard was agreed upon, leading to possible compatibility problems.

Another possible issue raised was possible delays in implementation of new devices, due to European trade guidelines.
Simulated tests
For the second phase of the overall study, the researchers designed three clinically relevant scenarios – spinal anaesthesia, epidural analgesia, and intrathecal chemotherapy. Thirty clinicians were recruited to take part using two prototype systems from device manufacturers.

Each clinician performed a simulated procedure, first using standard equipment and then the new devices on an anatomically realistic spinal trainer dummy. The first round of testing generated several recommendations for the manufacturers to take on board so they could make modifications before a second round of tests.

One manufacturer was told that relying on a detachable adaptor was not enough of a safeguard against possible misuse or bypass in a complex clinical setting. In the case of the other manufacturer’s device, the second round of tests were more positive and generated more favourable feedback. None of the clinicians participating said the system was unacceptable in its current form.

After competition from device manufacturers to take part in planned trials, eventually the Neurax non-Luer system was chosen.

Trialing new devices in hospitals
For this third and final phase of the study, the researchers investigated how well five different types of non-Luer equipment – all incorporating one manufacturer’s non-Luer connections – worked in practice by trialing them at four volunteer NHS trusts in Leeds, Sheffield, Birmingham and West Yorkshire.

The system chosen was Neurax, a specialised connector system designed to enhance safety by being glued, welded or moulded on to specific small-diameter tubular medical products such as needles and syringes, drug containers and flexible fluid-conducting tubes.

The devices were used in the preparation and administration of intrathecal chemotherapy and spinal anaesthesia. These non-Luer trial devices were used to administer 362 intrathecal injections as part of spinal procedures over a three-month period.

The equipment trials took place in various clinical contexts (paediatric and adult haematology, theatre anaesthetics, and obstetric anaesthetics).

During the trial period, the researchers gathered data regarding the acceptability of the equipment and the way in which it was introduced using four methods:

- observations of use
- interviews with healthcare professionals
- administration of post-trial questionnaires
- debrief session discussions.

The results of all this collected information showed that many users supported the concept of non-Luer equipment for intrathecal injections and felt its introduction would have a beneficial impact on patient safety.

Support was stronger in the case of intrathecal chemotherapy, while anaesthetists were less convinced of the safety benefits in their context of care.

However, most people using the new equipment felt it was more difficult to use than standard Luer devices and a wide variety of problems were encountered by clinicians. These included difficulties with inserting spinal needles, needle placement, connecting syringes, injecting intrathecal agents and drug leakage.

Pharmacy technicians generally experienced fewer difficulties, but did have problems with opening device packaging, drawing up drugs, transferring drugs between syringes and confusion related to the presence of adhesive used to attach Neurax connectors to syringes.

The feedback the researchers got during the equipment trials suggested that most clinicians would
be happy to use the new devices but not in their current form.

These pieces of equipment were prototypes, the researchers said, which explained many of the difficulties in using them that were reported by the clinicians trialing them.

Many users said that by making a series of minor modifications, the new devices could be as simple to use as the existing Luer equipment.

**Guidance on implementation**

The researchers also set out to provide implementation guidance during the trial and for the wider roll-out of non-Luer intrathecal equipment in the future. Several factors would help to ease implementation of such devices, they said, such as:

- extensive user involvement
- clear advertising of the date for switching to the new equipment as well as the removal of all Luer spinal packs from the clinical and pharmacy areas
- a comprehensive training package (comprising of training videos, demonstration equipment, and sharing of expertise from confident users)
- careful co-ordination between relevant groups of healthcare professionals when change-over from Luer to non-Luer takes place.
- consideration of storage, packaging and labelling

**Summary of main findings:**

- During trials of non-Luer devices, healthcare professionals were enthusiastic about the new devices and supported their introduction in intrathecal chemotherapy, but less so for use in spinal anaesthesia
- New connector devices will work well in intrathecal chemotherapy and not introduce any new hazards
- Clinicians in anaesthesia are not convinced the new devices will help tackle the problem of spinal drug errors
- Colour coding for the new connector devices is not foolproof because there is no universally agreed standard for delivery routes and different manufacturers use different colour-coding systems
- Two of the prototype non-Luer medical connector devices showed they could prevent a syringe being attached mistakenly to a spinal needle
- The new devices were potentially hazardous if they were not made translucent, which helps clinicians to see what a needle is doing and if it has reached the right place during injections
- During trials of five new connector devices, clinicians found problems with drug leakage, connecting devices together, and spinal needle placement.

**Conclusions, recommendations and implications for practice and policy:**

- Clinicians' willingness to adopt the new non-Luer devices is promising when the design issues identified in the study have been resolved, because most believe patient safety will benefit from implementing these devices
- Implementing the new devices will have a different impact in different settings, with some clinicians welcoming them and others resisting them
- When introducing any system of non-Luer equipment for intrathecal injections into the NHS, it will be necessary to ensure this implementation is carefully considered to make the transition as smooth as possible
• For implementation, there should be advice on a training and familiarisation period, setting a date for transfer to new equipment, clearly advertising this date, the removal of all Luer spinal packs from the clinical and pharmacy areas, and consideration given to storage and packaging of non-Luer devices

• Future research could be done into the potential development of an identification system for medical connectors that combines colour and shape coding to make it safer and easier to select and use the correct connectors in complex, time-pressured situations

• Removal of the rotating collar on the new equipment (or replacement with a fixed collar) and further evaluation of the devices is required before final implementation.
2.1.4 Correct site surgery alert – how trusts responded

Professor John Wright

Key Messages:

- Before the NPSA alert, marking of patients before surgery was not universal practice amongst clinicians and there was little evidence of formal or standard policies for this practice.
- The NPSA alert increased the numbers of surgeons marking patients before surgery and promoted greater awareness of safety issues related to correct site surgery.
- The alert also had unintended consequences such as greater bureaucracy and prompted concerns from surgical staff that the alert could have adverse effects such as complacency and potential danger of mistakes in last minute marking of patients.
- There was a danger of concentrating on marking and giving insufficient attention to other important safety recommendations in the alert about how, where and by whom marking should be carried out.
- There are potential advantages from standardising marking practices, particularly as surgeons often work at different hospital sites.
- Future guidance on wrong site surgery should take into account the differences between specialties and the effect of local circumstances if it is to be effective.
- Although the alert helped to change marking practice, it did not always change underlying attitudes and not all surgeons were committed to the practice.

Background:

There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the Government.

A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year.

As well as setting up the NPSA in 2001, the Government launched a large scale research programme to:

- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective the attempts to reduce errors have been
- implement ways of guaranteeing change in people and organisations.

Wrong site surgery is one type of medical error that is uncommon, but which can have serious consequences. It is surgery carried out on the wrong side of the patient and/or the wrong anatomical location or level and can include surgery carried out on the wrong patient or performing the wrong procedure on the right patient.

Previous research has suggested the potential benefits of marking patients prior to surgery to help
prevent such errors.

Concerns about ambiguity and uncertainty among hospital staff on this issue prompted the NPSA to issue guidance on how to prevent wrong site surgery in 2005 in the form of an alert.

**Aims of the Study:**
The aim of the study was to evaluate the impact of a safety alert issued by the NPSA on pre-surgery safety practices, in particular the marking of patients, to see if surgeons were changing their practice as a result, 12-15 months after it was issued.

**About the Study:**
The researchers carried out face to face and telephone interviews with clinical leads and lead nurses in orthopaedics, ophthalmology and urology in 14 NHS trusts in England and Wales, four of which were Safer Patients Initiative sites.

**Practical findings:**
At the time, very little was known about how often wrong site surgery incidents happened because of a lack of willingness amongst health professionals to report incidents voluntarily.

**Marking practice before the alert**
The researchers looked at existing research on the issue, guidelines from the USA on measures to avoid wrong site surgery and a draft copy of the NPSA safety alert before it was issued.

This helped them to design a questionnaire asking clinicians about their surgical marking practices with five sections:

- experience of wrong site surgery
- general systems in place to reduce wrong site surgery
- marking for wrong site surgery
- other methods of identifying the correct site for a procedure
- views about the potential value of a national system for minimising wrong site surgery.

They chose to interview clinicians from three specialties considered to be at high risk of wrong site surgery – urology, ophthalmology and orthopaedics – at 14 hospitals in England and Wales.

This group included four hospitals that were part of the Health Foundation’s Safer Patients Initiative with the intention of perhaps finding examples of good practice.

Interviews were carried out face to face or over the telephone with a clinical lead (consultant) and a nominated nurse in each specialty.

From the 71 clinicians interviewed (36 consultants and 35 nurses), the researchers found that there was little evidence of formal or standard policies at trusts about marking patients before surgery. It was more often left to specialties to decide their own policy on marking patients.

In one department, a policy of marking had been dropped after an infamous case where wrong site surgery happened because of the patient being wrongly marked.

Most people asked had experiences of wrong site surgery from their past but it was difficult to detect a pattern or causes of these incidents.

Several incidents had happened despite the patient involved having been marked before their surgery. Patients of all but one of the orthopaedic surgeons interviewed were marked prior to surgery, but some urologists and ophthalmologists reported they did not mark or marked only for certain procedures, i.e. where removal of the wrong organ would have serious consequences.
Attitudes towards marking varied. Some surgeons believed that it could compromise patient safety by causing complacency while others regarded it as a necessary part of safe practice.

Those who considered marking as potentially dangerous thought so because of concerns about:
- risks of the wrong side or site being marked
- a tendency to rely on the mark rather than additional checks, especially when time was short
- potential communication difficulties – staff might think the presence of a mark meant the required checks had already been carried out and that there was no need to repeat them
- the possibility of marks being inadvertently rubbed or wiped off during surgical preparation
- encouraging too great a reliance on nurses’ ward and theatre checks at the expense of checking with X-rays and other sources of evidence
- reluctance to rely on a mark made by someone else.

The methods used in marking also varied with most surgeons using an indelible marker pen, but some used non-indelible pens, especially for facial marking.

Different people did the marking in different departments and some surgeons always marked their patients prior to surgery, while others rarely marked patients themselves. In some departments, marking was routinely delegated to juniors or even nurses. Those who marked were not always present in theatre.

**Marking practice after the alert**
The researchers then carried out follow-up interviews with the same clinicians 12-15 months after the alert was issued with a different questionnaire to see if their marking practices had changed since the safety alert was issued. This questionnaire covered:
- personal practice
- awareness of the alert
- views on guidance
- handling of guidance
- implementation in practice
- evidence of implementation
- monitoring/audit of implementation.

From the 70 clinicians interviewed (34 consultants and 36 nurses), the researchers found that news of the NPSA’s safety alert had disseminated through a number of means including clinical leads, all senior medical staff, nursing and medical channels, and/or risk management.

Successful dissemination happened when multiple methods had been used rather than using a single channel.

Some trusts adopted the recommendations of the alert as trust policy while others allowed individual departments to determine their own response.

In those places which had a top-down approach, there was some criticism that there had been inadequate planning and preparation, lack of consultation with clinical staff, treatment of the alert as a managerial policy rather than a clinical guideline, and a rushed timetable to meet deadlines.

The interviews revealed that circulating the guidance did not necessarily mean that it was actually read by staff or acted upon.

Most people interviewed said they were aware of the alert, but their memory of specific detail in its contents was often hazy and in some cases, wrong or they only remembered certain aspects of it.

Most had been made aware of it by their hospital or department, but some people could not remember how they had become aware, whilst others had heard about it through their professional body.
Some people interviewed were still not aware of the alert and at one hospital site, nobody spoken to was aware of the alert or had changed their practice.

**Opposition**
Opposition to the alert was greater among doctors than nurses and was based on factors such as the additional paperwork required – in particular the requirement to sign a form to indicate that checks had been done – a belief that marking would not improve safety and might even increase the risk of error, and reluctance to rely on a mark made by another doctor.

In three departments that were represented in the interviews – two ophthalmology and one urology – there was universal refusal to comply with the alert’s requirement to mark all patients before surgery.

Elsewhere, people complied even if they did not personally agree with the alert’s recommendations. Nurses felt that their medical colleagues were slower to accept change than themselves.

**Change in practice**
The researchers found there had been significant changes to clinicians’ practice as a result of the alert. Before the alert, 16 consultants overall marked patients for all surgery involving one side of the patient. After the alert had been issued, this rose to 31 consultants by the time the second interviews took place.

Orthopaedic surgeons, almost all of whom were marking prior to the alert, continued to do so. The majority of urologists and ophthalmologists, few of whom had been marking before the alert, were now marking for all procedures involving one side of the patient.

This change was not universal and some of those consultants who had been opposed to the practice of marking patients before surgery on the grounds that it could compromise patient safety, continued not to mark after the alert came out.

Most surgeons continued to use a black indelible marker and an arrow to mark patients, although some preferred to use less permanent markers.

The alert recommended that the surgeon or nominated deputy who would be assisting in theatre during the patient’s procedure should be the person who did the marking, but the interviews showed that, in many departments, marking was still delegated routinely to juniors.

Conflicts emerged between medical and nursing staff over the issue of marking – who did it, where and when it was done, and who was responsible for signing to indicate completion of checks.

There were several benefits that emerged from the NPSA alert, according to the clinicians interviewed, and these included:
- review of existing procedures
- reconsideration of the value of pre-surgical marking
- review of existing checklists and other documentation
- tightening up of the consent process
- heightened safety consciousness
- greater emphasis on team working.

**Safer Patient Initiative Hospitals**
The staff at the *Safer Patients Initiative* hospitals who were interviewed were not generally aware of the alert itself because it formed part of larger programme to improve patient safety in those hospitals.

However, this lack of awareness did not mean that they were not involved in implementing the recommendations of the alert and most staff were conforming to the recommendations about marking.

They considered a more significant change to be the introduction of a pre-theatre procedure briefing.
or “huddle” during which all theatre staff meet to discuss the surgery list before they begin procedures. This practice was not generally reported by the staff interviewed at the other hospitals.

Audit of case notes
The researchers also carried out an audit of case notes to review the implementation process of the alert and accompanying marking checklist.

Four hospitals were chosen for this audit and 100 sets of case notes were looked at from consecutive cases in each hospital – 35-40 in orthopaedics and ophthalmology and 20 in urology.

The researchers found it difficult to draw any meaningful comparisons from the four hospitals’ data that they studied, because the necessary documentary changes had not yet been made in all four sites.

Even in those hospitals that had introduced changes, both the documentation and the local expectations about how it was to be filled in differed, reflecting the variation in documentary practices observed from the whole sample of people interviewed.

Summary of main findings:
- The NPSA’s Correct Site Surgery Alert almost doubled the number of clinicians’ who changed their practice and started marking patients before surgery
- Although most staff said they were aware of the alert, their memory of its contents was often hazy
- Some medical staff were opposed to the safety alert because of additional paperwork needed to observe and follow its recommendations, and the requirement to mark patients before surgery
- Urologists and ophthalmologists did start to mark patients before surgery – a change in their usual practice – in response to the alert, but they still felt it compromised patient safety by inducing complacency
- In many theatres, marking was still delegated to junior staff who were not going to be present during the surgery despite the alert recommending it be done by the operating surgeon or nominated deputy who will be present in the operating theatre at the time of the patient’s procedure.
- Nurses often implemented sanctions against non-compliance with the requirement to mark patients and refused to allow patients to be released from their care until they had been marked, with the result that marking could be carried out in haste at the last minute.

Conclusions, recommendations and implications for practice and policy:
- Standardisation of marking practices has potential advantages, particularly where surgeons work at different hospital sites, but the differences between specialities and the impact of local circumstances need to be considered in future guidance
- Marking is likely to be effective only as part of a range of measures within a general culture of safety consciousness because no single measure is itself enough to prevent wrong site surgery
- Methods of dissemination in different trusts are variable and would benefit from a model of good practice
- The factors most conducive to successful implementation included: adoption of the recommendations as trust-wide policy; multiple channels of communication; local
consultation; clinical leadership; adaptation to the local context

- The alert was successful in promoting marking practice, but less successful in convincing all surgeons of its worth

- Because there was wide variation in the ways the new documentary requirements were interpreted, future guidance should keep documentary requirements to a minimum and give more explanation for the changes.
2.1.5 How effective is root cause analysis (RCA) training for NHS staff?
Professor Louise Wallace

Key Messages:
- Training in root cause analysis of patient safety incidents is worthwhile and encourages NHS staff to conduct systematic investigations into patient safety incidents
- Staff are enthusiastic about root cause analysis (RCA) but not always successful in applying it because of their trust's culture, systems, approach to the conduct of RCA and how learning from RCA is disseminated
- Further skills development and organisational support is needed to achieve continued improvement in practice and to sustain organisational learning
- Trusts should put in place an organised approach to cascade training through NHS organisations, and to periodic refreshing of such systems by introducing new expertise in RCA.
- If RCA is to become a real force for improving patient safety, staff have to be convinced that organisational learning is achieved from the process
- There should be greater emphasis on systems for learning across trusts that share similar services and between healthcare providers within a local area with facilitation by NPSA patient safety managers.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them.

Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government.

A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

In other high-risk industries besides healthcare, methods of investigation that use human factors are sometimes grouped together under the title of root cause analysis (RCA) as a way of investigating and learning from safety incidents.

This method aims to avoid personal blame of healthcare staff involved in incidents and to focus on the system's problems such as aspects of care pathways, managerial practice, competence and
This method was adopted by the NPSA in 2001 in England and Wales following the CMO’s report and a three day training programme was launched in 2003, which trained over 7,000 people over two years.

The NPSA has identified RCA as a key tool in improving patient safety and is keen to improve the effectiveness of RCA training.

**Aims of the Study:**
The study’s main aims were to find out:
- the extent of motivation and increased knowledge of RCA amongst delegates at the end of the RCA training course
- the extent to which this motivation and knowledge was sustained over time (minimum of 6 months)
- how the knowledge of RCA had been used practically within the delegates’ organisation
- the extent to which the delegates had interacted with other clinical and managerial colleagues to disseminate their knowledge and enthusiasm for RCA.

**About the Study:**
The researchers used several methods for their research including:
- a survey of staff, using questionnaires carried out at the end of the third day of the course and six months later
- examining eight case study sites where the researchers visited each site and conducted semi-structured interviews with risk managers, patient safety leads, and at least one member of staff who had conducted a root cause analysis
- the NPSA head of investigations critically analysing 10 exemplar root cause analysis cases against a template, derived from the 8 exemplar case study sites.

**Practical findings:**
The researchers started from the point that root cause analysis (RCA) methods require healthcare staff to respond to reported incidents by:
- undertaking a systematic process of investigation
- looking at factual reporting of events and timelines
- analysing contributory factors
- identifying possible causal links and system vulnerabilities
- formulating recommendations that aim to prevent it happening again which can be shared with other similar health organisations and regulatory bodies and formalised into guidance and changes in work routines.

The RCA three-day training had several objectives including giving delegates an understanding of the theory underpinning RCA; improving delegates’ attitudes towards a ‘systems’ based approach to patient safety incidents; providing delegates with the skills to carry out an effective high quality RCA; providing them with the tools and information to enable them to cascade RCA training within their organisations; and developing learning networks across and within organisations to develop and implement solutions aimed at reducing future patient safety incidents.

**Staff survey**
A survey of staff from various types of NHS trusts was carried out using questionnaires developed from a brief review of research, from consultation with safety experts, and with the NPSA.

The researchers obtained responses from 374 people at the end of their training course and responses from 350 people six months afterwards. Participants were risk managers who were often also clinicians, clinicians with an interest in patient safety, or non-clinical staff with risk management
responsibilities. They were asked about:

- their role in risk management/investigations
- decisions to use RCA
- beliefs and intentions about RCA using a psychological model called the Theory of Planned Behaviour
- detailed test of knowledge of RCA.

**Experience**

The researchers found that many (79.6%) staff had conducted a patient safety investigation prior to doing the training course and 30.7% had conducted an RCA.

Six months later, the percentage of people who had conducted an RCA almost doubled to 58.3%.

Knowledge test scores from the survey showed that the course was giving participants an accurate understanding of key concepts such as types of error, barriers of error, and defining violation errors.

However, tests using knowledge as applied to specific scenarios were less promising and in one scenario in which the specific type of error had to be identified, only 42.5% of people did so correctly, while analysis of care and service delivery problems were only judged correctly by 51% of participants.

The researchers also found that the correct result of a case study scenario was given by only 49.5% of participants who gave a non blame/supportive outcome. Almost half (47.1%) of participants suggested punitive (counseling and/or disciplinary) actions should result, but this was incorrect and suggested, said the researchers, that participants were reflecting organisational cultures of their own NHS trust.

**Attitudes and confidence**

Overall satisfaction with the training was high and the vast majority (85.2%) of staff said the RCA training was quite or very helpful at the time of the course and 72.9% said so six months later.

The roll out of RCA within trusts seemed to rely on two models – internal cascade (passing on of knowledge via internal training by those who had attended the NPSA course) or reliance on the NPSA’s three day training and related programmes.

People taking part in the survey reported that their trusts expected to train, on average, around 15-30 staff with rising numbers over the following year.

More than 80% of staff were confident about applying RCA at the time of the course and six months later, but only half were confident to train others. At the time of the training course, only a fifth said they were confident they could pass on RCA training to others and this rose to about a third six months later.

Staff were increasingly confident that using RCA would make a difference at their trust, shown by the fact that 46% said at the time of the course that it would reduce patient safety incidents in their trust, but this rose to 62% who thought it would when asked six months later. Implementation was a more difficult issue and at the time of the course, 23.2% of staff felt it would be easy to implement RCA as standard practice at their trust and this only rose to 43% six months later.

**Barriers**

All staff said they experienced barriers to implementing RCA including:

- lack of time to do RCA properly and for staff to attend in-trust cascade RCA training
- difficulty in getting people to agree to lead on an RCA
- conflict between improving patient safety by RCA and meeting performance targets
- no adequate system in place to cascade RCA training
- the trust did not implement actions from the RCA
• conflicting or absence of policy directives within the trust about the investigation and disciplinary process.

Outcomes
Staff were asked about the outcomes of RCAs and of the 59% who said they had conducted an RCA since the course, 87.6% said the outcomes and learning were reported within the trust.

Only a third, however, were aware that these outcomes had been reported to external bodies such as their strategic health authority.

Even fewer (6.2%) believed outcomes had been reported to the NPSA’s National Reporting and Learning System.

Case study sites
Eight case study sites were chosen by consultation and nomination via the NPSA, strategic health authorities and trust risk management leads.

The researchers visited each of the eight sites and conducted semi-structured interviews with risk managers, RCA leads, and at least one member of staff who had conducted an RCA. The case studies were designed to address the following questions:

How well did NHS staff apply the approach, as taught by the NPSA, and what was the influence on:
• organisational structures and processes for risk management and for risk incident management and investigation?
• organisational culture and individual/organisational/multi-organisational learning?
• how fit for purpose were example RCA investigations in sites that were regarded as likely to show effective application of the NPSA’s RCA approach?

Seven trusts provided 10 examples of RCA investigations, which were critically reviewed against an RCA template. Two trusts submitted cases that were excellent examples of application of RCA as taught by the NPSA, while three trusts gave examples with partial use of RCA, and considerable good practice, and two submitted cases that did not conform to the RCA approach.

Good practice was apparent in the use of a wide range of techniques, use of external experts and group facilitation methods, the identification of Care/Service Delivery Problems or issues, contributory factors and root causes.

The researchers found there were some weaknesses, including the most complete RCAs, that required more focus on use of Care/Service Delivery Problems or issues, contributory factors and root causes, because these are integral to understanding the causes and possible remedies and preventive actions.

They concluded that there should be greater emphasis on the use of best practice guidance available nationally (electronically) from the NPSA during training and after training support/cascade.

Another way to help motivate staff to use RCA to a high standard would be for feedback on completed RCAs by the NPSA to be given via patient safety managers or national channels.

The researchers’ interviews with staff showed that the NPSA was felt to be a credible organisation and people felt it had produced well regarded training and guidance.

All of the sites showed enthusiasm for RCA, but how successful they were in applying it was varied, depending upon the influence of the trust’s culture, systems, and approach to RCA.

Learning across trusts and externally was very limited and there was dissatisfaction about the low perceived input from patient safety managers and strategic health authorities.

Some staff said their organisation struggled with the concept of public and patient involvement in risk management and in RCA in particular.
The researchers found that some new in-house short courses were being undertaken in parallel to trust-based cascade training.

**Summary of main findings:**

- Large numbers of staff (85.2%) who had the training rated it highly as ‘quite’ or ‘very’ helpful
- Most staff achieved a good knowledge of root cause analysis from the training and were actively involved in conducting it later
- Excellence in root cause analysis depends upon leadership and the enthusiasm of individuals as well as supportive structures, processes and culture compatible with root cause analysis
- Learning happens mostly within trusts and systems for sharing and learning outside of trusts are almost non-existent
- Numbers of people who have conducted a root cause analysis almost doubled from 30% to 59% six months after doing the RCA training programme
- Feedback from strategic health authorities on root cause analysis carried out within trusts is poor
- Staff who underwent RCA training had difficulties in implementing it back at their trusts because of problems passing the knowledge on and undeveloped systems for sharing learning

**Conclusions, recommendations and implications for practice and policy:**

- The RCA training was highly successful, achieved good results in knowledge of the conduct of RCA and inspired confidence in participants
- The difficulties of implementation in trusts highlights the need for support to trusts after the course and continuing development of skills in applying RCA
- There should be accreditation of ongoing RCA continuous professional development and the NPSA should focus effort on building resources to support trust staff in cascading RCA practice and ensuring the quality of training within trusts is at least as good as that provided directly by the NPSA
- Because some new in-house short courses were being undertaken in parallel to trust-based cascade training, new models of ongoing training for those who attended the original RCA networked training, and the use of alternative models of roll out to other staff should be formally evaluated
- Learning of RCA would be improved by people taking part in model anonymised RCAs to build their competence and using problem-based learning approaches
- The NPSA should disseminate widely real examples of RCAs and how they are implemented to build skill in knowledge, overcome organisational barriers and demonstrate the impact they have on safety
- The NPSA has developed a one and two day RCA training programme (both generic and a targeted Mental Health programme) which should be evaluated.
2.1.6 How well do NHS trusts react to patient safety alerts?

Dr Peter West

Key Messages:
- Patient safety alerts and their importance are viewed quite differently at different trusts, which do not have a uniform approach in this area.
- Front-line clinical staff do not always get access to the information about alerts that should be disseminated to all staff, so work is needed on IT provision and education at ward and clinic level.
- Safety Alert Broadcast System (SABS) liaison officers need either to be at, or receive support from, senior level for what is an important and responsible job.
- Someone with seniority and a clinical background should be involved in all decisions regarding clinical alerts at every trust.
- Alerts that require changes in the behaviour of doctors and nurses should be marked for action by both medical directors and directors of nursing.
- Trusts should review their SABS policies in the light of experience.
- How well a trust responds to a safety alert depends on the complexity of the alert and the strategy at that trust.

Background:

There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the Government.

A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the NPSA in 2001, the Government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective the attempts to reduce errors have been
- implement ways of guaranteeing change in people and organisations.

The Safety Alert Broadcast System (SABS) was set up by the government in 2004 as an electronic system designed to disseminate the patient safety alerts issued to the NHS by various official bodies including the NPSA.

The system requires trusts to feed back to the Department of Health's patient safety team on the relevance of the alert to them, what action they took, and when that action was completed so that their performance in implementing alerts is monitored.
Aims of the Study:
The study’s main aims were to:
- determine how SABS directives are disseminated and acted upon in trusts
- identify how the SABS system could be improved
- determine whether, and how quickly, a range of alerts were implemented
- identify, in cases of non-compliance, what prevented implementation of the requirements of the alert.

About the Study:
The researchers focused on four steps in the process of issuing a safety alert to the NHS – receipt of the alert; disseminating it; implementing it; and monitoring action taken.

They carried out the study in two phases, the first being a high-level study investigating the dissemination and monitoring processes used by NHS trusts as well as the monitoring processes undertaken by strategic health authorities.

The high level study comprised:
- interviews with key stakeholders in bodies that issue safety alerts and the Department of Health
- a survey of SABS liaison officers in acute and primary care trusts
- telephone interviews with those in strategic health authorities responsible for putting alerts into action and monitoring the performance of trusts in respect of SABS.

The second phase involved an in-depth study of 11 alerts by visiting 20 acute trusts, 15 primary care trusts (PCTs), four ambulance and two mental health trusts.

The site visits to trusts comprised structured interviews with staff responsible for disseminating and implementing alerts, and audits to assess how much they implemented. The researchers also interviewed GPs and practice managers.

Practical findings:
Alerts and action taken
The researchers began their work by analysing the 95 alerts issued between October 2006 and June 2007 from the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health’s Estates and Facilities division, the NPSA and the Department itself.

A wide range of subjects was covered in these alerts including safer medication practices; the testing of naso-gastric tubes, colour coding cleaning materials; use of bed rails as ligature points; identification of blood; fixtures, fittings and design; helicopter landing areas; process for dissemination of alerts; medical equipment; and security in medium secure psychiatric units.

The researchers used the SABS system on a particular day at the end of the nine-month period on which they were focusing to determine what progress had been made on the alerts issued during that time. They found significant variations across trusts in their responses to the SABS system and between types of trust, with PCTs seeming to have more trouble in implementing alerts.

Further analysis of 52 alerts, for which trusts should have taken action by the time that the system was being studied, showed that 91% of trusts had recorded that they had completed action or declared that action was not required.

Survey of liaison officers
Every trust has to have a named person as the SABS Liaison Officer (SLO) who receives the electronic alerts, is responsible for passing them on to the most appropriate person and then notifying the Department of Health when the required action is taken.

The researchers carried out an electronic survey of SLOs in the NHS between June and September
2006 and gathered 343 completed questionnaires – a 61% response rate.

The researchers noted the wide variation in level of seniority and authority of some of the SLOs who reported 216 different job titles, mostly related to clinical governance, risk, or health and safety. The officers responding had various backgrounds including 35% who had a clinical background and 34% who were in administration or career management.

Time spent on their SLO role varied amongst the people who responded to the survey ranging from just 2% of their time to more than 25%.

When asked about the dissemination of the alerts in the organisation, 65% of the SLOs said their organisation had a formal policy or procedure for the dissemination of patient safety alerts, 12% said this was in draft format and 22% that there was no formal policy.

The researchers found that SABS liaison officers had some technical problems such as time delays in acknowledging receipt of the alert (up to 20 minutes) and in recording that the alert had been completed (weeks, sometimes).

Nine people also mentioned the sheer number of alerts being a problem, but for most of those who commented (47), the problem was one of poor targeting – a particular issue for people from PCTs and mental health trusts.

Generally, people felt it was easier for the bodies who issued alerts to opt for blanket coverage, but this created more work for SABS liaison officers in trusts and introduced a potential danger that the important alerts would be underestimated because of the number coming in.

Some SLOs (42%) made decisions on the relevance of a safety alert with no independent scrutiny of their decision.

As many as 71% of respondents said they disseminated only those alerts deemed relevant to their organisation, while 28% disseminated all alerts. Those with a clinical background felt that they had an advantage in judging where to send the alerts.

Around a third (32%) of officers said their trust had never audited the implementation of alerts and 11% said such an audit had only happened once. These figures may overestimate the reality given that an audit of alerts may entail only an audit of the SLO records, rather than of a change in practice on the ground.

Visits to trusts for in-depth study
For this part of the study, the researchers chose, randomly, 20 acute trusts, 15 PCTs, four ambulance trusts and two mental health trusts where they interviewed relevant staff about the management, reception, dissemination and implementation of alerts.

They chose 11 ‘tracker alerts’ to study so that evidence could be collected on implementation. These included alerts on protecting people with allergy associated with latex; safe delivery of radiotherapy; alcohol based hand rub; electrically operated beds; and reduction of the risk associated with problems with implantable cardioverter defibrillators.

Interviews with managers
During the visits, the researchers interviewed 91 senior managers including directors of nursing, medical directors, chief pharmacists and clinical governance directors in addition to 33 SLOs.

They found that SABS liaison officers in acute trusts were more likely to be senior managers or be managed by a senior manager than in PCTs, where senior managers tended to have a more ‘hands-off’ approach to alerts. There was also evidence of more direct involvement of senior managers in decision-making and taking action in acute trusts.

The processes for making decisions on the relevance of alerts to the organisation were not always well set out and the researchers expressed concerns that these decisions and those on dissemination were not always adequately scrutinised.
Most organisations had good systems for distributing SABS alerts to managers and to one lead person at ward and clinic level. However, systems for sharing alerts amongst all ward and clinic staff were less well developed.

There was much to recommend the system and 36 (72%) senior managers interviewed believed that the SABS system had advantages over previous systems.

Examples of advantages included:
- a single point of entry to the system
- clearer accountability as the system ensures that trusts have to acknowledge receipt and report action on alerts
- simple formatting of alerts which are mostly more focused and specific
- streamlined and quick electronic delivery system
- ability to set up an organised tracking system within a trust, and internal reliable archives in the trust.

Several improvements to the system were identified by people interviewed, including better targeting of alerts; using more appropriate language in the alerts; clearer and more concise alerts; alerts from several sources now coming through one system; and more appropriate grading of alerts to risk and importance.

Overall, the researchers found that implementation of the ‘tracker alerts’ was mixed and how effectively they were implemented depended on how complex the alert was and strategy at a particular trust.

**Interviews with front-line staff**
The researchers also visited up to 10 wards in each trust relevant to the specified alerts being studied to carry out interviews with one front-line member of staff in each area (usually a ward sister or nurse in charge).

In all, 393 interviews took place with a range of key staff at the acute trusts, including 170 ward interviews and audits. In PCTs, 171 face to face interviews and 95 telephone interviews took place, while at the ambulance and mental health trusts, there were 32 and 29 interviews, respectively.

They also audited the availability of policy documents and collected evidence of implementation of alerts from an audit of equipment (such as latex products and mobile food trolleys) and documentation.

Overall, the researchers found that although some action had been taken in all acute and mental health trusts for all of the alerts, not all ward managers interviewed were aware of the recommended action in respect of Latex allergy or the testing of nasogastric tubes.

PCTs, many of which had been subject to merger, were less likely to have taken appropriate action.

**Primary Care**
From interviews with SABS liaison officers, managers in PCTs, and general practice managers, the researchers found that alerts were distributed to independent contractors such as GPs and dentists, by e-mail, fax or hard copy in the post.

Of the general practice managers and managers in PCTs interviewed, only 22% said their GP practices thought the alerts were mostly helpful, while 57% said they were mostly irrelevant.

**Interviews with strategic health authority managers**
The researchers also carried out telephone interviews with 15 people from nine out of the 10 strategic health authorities in England. These people had responsibility for SABS in their organisation.

Most of the people from strategic health authorities spoke about the inaccuracy of the data on the SABS webpage reports, with data being different in trust reports to health authority reports.
Thirteen of these people said they monitored the performance of trusts and PCTs including monitoring of action underway and action completed. Nine monitored outstanding alerts, varying from daily and weekly through to annually, but only four produced reports to be submitted to their board.

Overall, most people commenting thought SABS was useful for helping strategic health authorities to monitor trusts’ performance, depending on how actively involved the SABS lead person was.

Summary of main findings:
- There were significant variations across trusts in their responses to the SABS system and between types of trust
- More than a fifth (22%) of organisations do not have a formal policy or procedure for managing patient safety alerts
- Awareness of the requirements of particular alerts is patchy amongst front-line staff at NHS organisations
- Around 10% of trusts are failing to take action on alerts by the called-for deadline time
- Just over a quarter (28%) of SABS liaison officers disseminate all alerts sent to them and 71% disseminate only those alerts deemed relevant to their organisation
- Around a third (32%) of SABS officers said their trust had never audited the implementation of alerts
- Most NHS organisations have good systems for distributing safety alerts to managers and lead clinicians but systems for ensuring alerts are read by all ward, clinic and ambulance staff are unaudited and inadequate.

Conclusions, recommendations and implications for practice and policy:
- Some SABS liaison officers have a relatively low level of seniority/authority and trusts should ensure these officers have authority or immediate access to senior managers
- Alerts should be targeted better
- Terminology in alerts should be familiar to NHS staff and more concise versions should be developed for GPs and front line staff
- There should be more appropriate grading of alerts for risk and importance and each trust should develop a systematic strategy for assessing their impact
- There should be sequential numbering of alerts rather than numbering for each type (alert, safer practice notice etc)
- Systems to assess the relevance of alerts with properly assigned responsibility should be tightened at trusts with someone with a clinical background involved in decisions
- Each trust should take prompt action to ensure alerts are fully implemented before signing them off on the SABS website.
Chapter 3 – Medication Error

3.1 Introduction

Professor Nick Barber
Professor of the Practice of Pharmacy, University of London

When I was being trained, legislation relating to medicines was in the Pharmacy and Poisons Act. While that has now been replaced, mainly by the Medicines Act, it serves as a useful reminder of the nature of medicines contains the risk of harm as well as benefit. While the risk of harm from taking medicines is partly a consequence of the medicine itself, the role of human error has been increasingly recognised as compounding – probably doubling – the risk of harm. To some extent adverse drug reactions are a necessary risk of treatment, however harm resulting from the actions of health professionals (and, some would argue, patients) should be as avoidable as it is currently common.

Medicines are the most common form of treatment, and the second largest cause of expenditure in the NHS (following staff costs). The scale is vast – around 2 million prescriptions a day written in the NHS and drug expenditure of over £12bn a year. Admissions to hospital as a result of avoidable harm from medicines are around 5% of all admissions – a similar admission rate to cancer – leading to untold patient (and family) misery and leading to substantial extra costs on the NHS.

Most studies show prescribing error rates of 5-10% and nurse administration errors of a similar size – that means several errors a second happening in the NHS during normal working hours. While most of these do not cause any harm, the large volume of prescribing and administration of drugs means that if only 1 in 100, or even 1 in 1000, errors lead to harm then there is an enormous, and unacceptable, burden of misery and harm.

At the start of the PSRP there was relatively little work on medication errors in the UK, and much of that was in the pharmacy literature, reflecting the professions' role in making the use of medicines safer, and in primary care research. The papers presented tell the story of the PRSP engagement with medication errors – mapping the extent of the problem and suggesting and evaluating solutions. The first report (Karnon et al) scoped the problem and tackled the difficult problem of estimating cost effective solutions, given the limited literature and under-development of economic appraisal of these issues. Children are at particular risk of medication error – amongst many factors that contribute to this, the miscalculation of the correct dose is probably the most harmful. Wong et al studied the literature and practice to find the best methods to reduce these dosage errors. Of the solutions in the previous two papers, pharmacy services and technology play a significant role in error reduction. The studies led by Cantrill and myself address the issue of using information technology in hospitals to reduce medication errors, and show it can be effective in the UK. Finally, there are two large studies in primary care (where most medicines are used). I have led one into the extent of, and causes of, all types of medication errors in care homes. Avery is leading a large multidisciplinary intervention trial in primary care to reduce prescribing errors.
3.1.1 Medication errors – what is the best way to reduce their impact on patients’ health?
Associate Professor Jonathan Karnon

Key Messages:
- There is a lot of uncertainty when it comes to the benefits of specific interventions to help reduce medication errors and their impact
- There is a real lack of useful, UK-specific research on medication errors
- The type of medication errors that can happen in healthcare are almost infinite
- Future studies have to look at adverse drug events alongside medication errors if they are to be of any use in identifying interventions that reduce the health effects of such errors
- Computerised physician order entry systems (a form of electronic prescribing) and having extra ward pharmacists around have more potential to reduce medication errors than bar coding systems
- Interventions such as electronic prescribing and having extra ward pharmacists can save money and improve patients’ health
- NHS organisations should think carefully before they implement interventions aimed at reducing medication errors because studies have shown that a range of unforeseen negative consequences can occur, such as new types of medication errors.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and system errors. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS. It estimated that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Medication errors play a large role in adverse events in the NHS and there is little UK research around on the health impact of these errors.

Aims of the Study:
The study aimed to help fine tune where future research priorities should be in order to reduce the impact of medication errors (in the hospital setting) on costs and health outcomes.

The objectives were to:
- undertake a prospective analysis of hazards and improvements for potential interventions
that would identify the range and likelihood of medication errors at different stages of the
medication pathway
• describe how such interventions would impact on the occurrence and detection of
medication errors at different stages in the medication pathway
• undertake a thorough review of existing research on the incidence of medication errors and
adverse drug events, and the effectiveness of interventions
• interpret and supplement the data obtained from the research review based on the views of
experts from a range of relevant disciplines.

About the Study:
The researchers set out to study medication errors and how they can be reduced, using several
methods. An analysis of hazards and improvements in relation to medication errors was carried out
looking at types of errors, why and when they happen, solutions and what impact the solutions might
have.

The researchers also reviewed existing relevant research, held a two-day workshop with experts to
get their input on the subject, and then came up with a model to try out possible cost-effective
interventions, in theory, on adverse drug events.

Practical findings:
The researchers define “medication errors” as those that “include prescriptions that have never been
considered appropriate for the diagnosed condition, and preventable events that cause a deviation
in the medication received by an inpatient from an appropriate prescription intended by the
prescriber, excluding patient noncompliance.”

The main impact of medication errors is the subsequent experience of an adverse drug event, which
is defined as “an unwanted or harmful effect that occurs as a result of a medication error”.

Analysis of hazards and improvements
Firstly, the researchers used a prospective hazard and improvement analysis to describe the stages
of errors within a hospital. At each error stage, the analysis described the types of errors that can
occur, the causes of the errors, and listed possible solutions.

The medication pathway – the process beginning with a clinician’s decision to prescribe a drug right
through to actually giving it to the patient – was used by the researchers to identify error
opportunities and potential solutions. Using an existing detailed medication pathway for the
management of moderate and severe depression, the researchers adapted this to create a simpler
generic model structure that allowed them to estimate the cost and health impacts of medication
errors in a hospital setting.

The effectiveness of potential interventions was estimated by describing the impact of the
interventions on the errors made during the medication pathway.

A review of relevant existing research showed there was a range of data about how often medication
errors happened, though the definitions of error types and stages in medication pathways were not
consistent, and not directly comparable. They found that data describing error detection rates, the
health impacts of medication errors, and the effectiveness of potential interventions, were not well
covered. Four areas were studied:
• Medication error rates
• Detection rates for alternative errors
• Proportion of undetected errors that result in harm to the patient
• Levels of severity of adverse drug events that happen.

Resources and savings
The researchers came up with four broad categories of the impact of interventions:
• Intervention implementation costs
• Cost savings due to reduced treatment costs for adverse drug events
• Cost savings due to reduced resource use unrelated to adverse drug events (i.e. efficiency savings)
• Monetary valuations of the health benefits due to prevention of adverse drug events.

By looking at other studies, they found the costs for electronic prescribing systems vary, ranging from £0.4 million to £4.9 million for implementation and up to £1 million for ongoing annual maintenance costs. Using a pharmacist to accompany a doctor/nurse during their rounds in a hospital ward on an average 400-bed hospital means employing an extra seven pharmacists a year, said the researchers, at a collective annual cost of up to £0.4 m.

Using a bar coding system for drugs can cost anything between £0.4 m and £0.7 m, other research showed, although it was difficult to be precise.

All of these estimated costs have been updated since this paper was released and can be seen in two subsequent journal reports: Journal of Health Services Research & Policy Vol 13 No 2, 2008: 85–91 and J. Karnon et al. / Safety Science 45 (2007) 523–539.

**Expert opinion**
The researchers held a two-day workshop to which they invited a group of experts including GPs, hospital clinicians, a public health doctor, pharmacists, a nurse and human factors experts.

These experts were asked to come up with boundaries for error frequency and detection as well as estimates of the effectiveness of alternative interventions.

However, the workshop was only partially successful, and many of the boundaries could not be estimated by the assembled group.

The experts also helped to develop the medication error pathway used by the researchers.

**Model analysis**
The researchers came up with a model that was adjusted to calculate values for preventable adverse drug event rates by type of event and when it began in the medication pathway. Using this model, they estimated cost values for three interventions: computerised physician order entry systems or electronic prescribing (a process of electronic entry of a doctor's instructions for the treatment of patients under his/her care which communicates these orders over a computer network to other staff or departments) responsible for fulfilling the order

• additional ward pharmacists to help at the prescription stage of the medication pathway
• bar coding systems at the administration stage of the medication pathway.

Potential efficiency savings from using electronic prescribing systems were included. The analysis also took into account the necessary resources for the additional treatment caused by adverse drug events, and monetary valuations of the health effects of these adverse events on patients.

Estimates of the effectiveness of the three interventions were helped by the review of existing research and workshops because there was no direct evidence of the impact of the interventions at different stages of the medication pathway.

Using the model, the researchers came up with estimates of the benefits of these interventions over a five year period, taking into account the cost of implementing and maintaining them.

**Electronic prescribing**
The researchers found that electronic prescribing systems could have a significant impact on knowledge-based errors as a result of automatic computerised decision support systems that can show, for example, known allergies and drug contra-indications for a particular patient.

Well designed electronic prescribing systems were also likely to reduce wrong dose, wrong route
and frequency of prescription errors but could be less effective in preventing wrong drug prescription errors. Electronic prescribing systems could also help prevent some dispensing errors.

**Extra pharmacists**
Increased availability of senior pharmacists to help doctors and nurses on ward rounds and to be on-call could impact positively on the medication pathway and improve the accuracy of prescribing and spot mistakes, the researchers found.

**Bar coding**
Using bar coding should help prevent errors at the administration stage of the medication pathway because it identifies whether the correct medication has been selected for each patient.

However, the researchers warned that bar coding could make detection of prescription and dispensing errors less likely because nurses could assume a medication was correct because it had been identified as correct by the bar coding system without double checking it themselves.

**Preventable adverse drug events**
The researchers used a scenario of an average 400-bed hospital with 162,000 prescription orders a year.

They found that using a computerised physician order entry system or having extra pharmacists meant the number of preventable adverse drug events could reduce from an average 450 a year to around 300 a year, in both cases.

Using a bar coding system could mean less of an impact, reducing events from 450 to just under 400.

Significant cost savings could also result from using an electronic prescribing system or having extra pharmacists which reduce adverse drug events and therefore the need for more treatment, they found.

Instead of an estimated health service cost of £1-1.5 million per year for the 400-bed hospital with 162,000 prescription orders, using these two interventions could decrease the cost to around £0.75m.

Bar coding could reduce costs to a lesser extent – £0.9 million.

The monetary value of lost health due to preventable adverse drug events was on a much higher scale, said the researchers, who estimated that around £20 million could be lost with no interventions in the hospital scenario they used.

However, by using an electronic prescribing system or having extra pharmacists could reduce this to £14m, or using a bar coding system might lower it to £17m.

**Benefits**
The researchers found that significant benefits on the number of adverse drug events and the associated costs were likely if all three interventions were adopted. They raised some concerns about the cost of implementing an electronic prescribing system because if this was too high, it would cost more than the money it would save by using it.

Despite this, they concluded that taking the costs of the interventions, the cost of savings due to avoiding adverse drug events, and the monetary value of the health impact of avoiding adverse events all together, the net benefits were large.

Over a five-year period, this combined predicted benefit from using an electronic prescribing system could be in the region of £30 million.
Summary of main findings:

- Using an electronic prescribing system and having more pharmacists around could reduce the number of preventable adverse drug events significantly
- The costs associated with using an electronic prescribing system vary hugely from £0.4million to £4.9m to implement them and from £0.1m to £1m to maintain them annually
- In an average 400-bed hospital, an additional seven pharmacists are needed to accompany doctors/nurses on ward rounds and be on-call to look out for medication errors – costing around a third of a million pounds a year
- Using an electronic prescribing system or ward pharmacists can reduce health service costs by almost half because they cut the number of adverse drug events and thus the treatment that those events lead to
- Over a five-year period, around £30million could be saved by using an electronic prescribing in a hospital with 400 beds because of the benefits of less adverse drug events and better health of patients.

Conclusions, recommendations and implications for practice and policy:

- Future research could look at the relationship between medication errors and adverse drug events from a UK perspective
- It will be difficult to have precise and standardised models for spotting and dealing with medication errors because there are infinite types of medication errors with their own probabilities of being detected and different resulting severity of harm
- Careful design of electronic prescribing systems is required, which is specific to the health care system in which it is implemented. This is because existing ones have been shown to add new errors to those that the system is trying to prevent
- NHS organisations or researchers developing interventions similar to those studied in this research should have extreme attention to detail in developing and evaluating those interventions because there is variation in their reported effectiveness
- If future research confirms the cost-effectiveness of additional ward pharmacists, the capacity of the NHS to employ more pharmacists will be a key factor in implementing this intervention. Supply issues will have to be considered
- Future studies of critical incidents could be undertaken to define the attributes of pharmacists that contribute most to the reduction of medication errors – these might identify interventions such as new training programmes for other health professionals
- Worthwhile research could be done to gather data on the severity of adverse drug events occurring in different intervention groups and additional research on the value attached to the prevention of such effects.
3.1.2 Electronic prescribing – safer, faster, better?
Professor Nick Barber

Key Messages:
- Electronic prescribing and a computerised closed-loop system that manages, dispenses and administers drugs have the potential to reduce prescribing and drug administration errors.
- How we measure the effectiveness of new electronic prescribing systems in hospitals in the future is important because electronic prescribing needs to be evaluated prospectively rather than retrospectively. This is due to the fact that errors spotted and corrected beforehand leave no trace found in retrospective studies.
- More staff time may need to be spent on medication activity as part of using electronic prescribing to improve patient safety.
- Technical systems are never perfect but should be continually developed and improved upon.
- How many errors are noted is heavily dependent on the method of detection.
- Retrospective reviewing of medical notes seems to be the most productive method for measuring drug errors.
- NHS organisations should regularly look at the effectiveness of electronic prescribing systems because they, the human systems around them, and the technology they link into, will continue to develop.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Medication errors are one of the most common types of medical errors in healthcare and in the NHS, using information and communication technology (including electronic prescribing) to reduce errors is a major strategy.

Aims of the Study:
The study aimed to develop and pilot ways of evaluating the impact that electronic prescribing systems in hospitals have on patient safety. Key objectives included:
- recommending a framework for the evaluation of electronic prescribing
- piloting a prospective evaluation of one system (Serve Rx) at Charing Cross Hospital,
London and pilot a retrospective evaluation of the electronic prescribing system at Queens Hospital, Burton upon Trent

- developing methods, based on patients’ notes, to identify the incidence, nature and severity of medication errors
- comparing the incidence and nature of medication errors detected prospectively from observation, and retrospectively, from patient notes.

**About the Study:**

The team evaluated two electronic prescribing systems – ServeRx which was being introduced to a general surgical ward at Charing Cross Hospital, part of Hammersmith Hospitals NHS Trust, and the Meditech system at Queen’s Hospital, Burton upon Trent; one of only three hospitals in the country which had implemented a hospital-wide system at the time of the study. Three methods of detecting prescribing errors were used:

- prospective detection by health care professionals, usually pharmacists, recording the errors identified in the course of their daily prescription monitoring
- retrospective detection by studying patients’ medical records to identify prescribing errors
- use of a “trigger tool” meaning a collection of indicators (23) such as abnormal laboratory values and drugs that may be prescribed as antidotes, used to trigger more extensive investigation into whether medication-related harm has occurred.

The research was groundbreaking in that it evaluated a system quantitatively and qualitatively to measure it and understand why it was the way it was. The researchers also observed staff at the hospitals, carried out semi-structured interviews and held group meetings with healthcare staff and managers.

The researchers started their work from the basis that electronic prescribing’s benefits, impact and potential dangers should be studied especially because it was current policy (at the time this work was done) to move to this kind of prescribing in all UK hospitals. They accepted, from considering other existing research, that it was possible electronic prescribing could increase errors and harm if technical systems were poorly designed and had inadequate data or a poor user interface, underlining the importance for people working with a system to understand and use it well.

Overall, taking all of the results together from the two hospital sites before and after the electronic prescribing systems were introduced, the researchers reviewed 357 admissions and found 8 cases of harm (2.2%) resulting from prescribing errors.

**ServeRx system**

This system was introduced as a test on a 28-bed general surgery ward at Charing Cross Hospital in 2003. It features:

- electronic prescribing, scheduling and administration software
- ward-based automated dispensing
- electronic drug trolleys.

This ‘closed-loop’ system combines electronic prescribing with electronically controlled stock cupboards, linked to electronic drug trolleys that uses bar coded patient identification to allow drug administration. At the hospital, the researchers compared four ways of detecting prescribing errors in the same group of patients: prospective daily detection by pharmacists; retrospective review of the patients’ notes; trigger tool and spontaneous reporting.

On the 28-bed general surgery ward they studied, there were eight drug rounds a day. Data on outcome measures were collected 3-6 months before ServeRx was introduced and then 6-12 months after. A before and after comparison was used at Charing Cross Hospital to examine what effect the system had on:

- prescribing error (detected by pharmacists’ daily inspection)
- medication administration error (detected by observation)
- checking of patient identity (observed)
- compliance with several other protocols and areas of good practice.
Meditech
This system was first piloted at Queen’s Hospital, Burton Upon Trent, between 1994 and 1996 and had been developed and customised before this study began. The Meditech system is an electronic prescribing system that uses wireless laptop computers operating as part of a powerful Hospital Information System. One essential difference between the two systems was that while ServeRx was only linked to the trust’s patient administration system for transfer of basic patient data and no links to the pharmacy computer system or to laboratory data, Meditech was one part of a bigger hospital-wide system linked to all other patient and laboratory data.

For Meditech, the researchers studied the impact across four wards – general medicine, general surgery, paediatrics, and medicine for the elderly – where it was introduced at different times. Both electronic prescribing systems were studied, by retrospective review of patients’ notes to detect prescribing errors, before and after each system was implemented. Both electronic prescribing systems were evaluated quantitatively and qualitatively and the researchers carried out observation of staff at the hospitals, semi-structured interviews and held group meetings with healthcare staff and managers to help understand what they were finding.

Practical findings:
From the before and after comparisons, the researchers studied 4,803 prescriptions and found prescribing errors were reduced from 3.8% to 2% after ServeRx was introduced. Of the 2,822 drug administrations observed, administration errors (excluding intravenous errors) fell from 7% to 4.3%.

Another highly visible change noted was the checking of patient identity before administering medicines, which rose from 17% to 81% when comparing the ward before and after it started using the electronic prescribing system. They also measured staff time and found that medication related activities increased significantly for all healthcare professions. From the retrospective study of patient notes, of 93 patients studied before the introduction of ServeRx and 114 after (who received a total of 2,872 prescriptions), the prescribing error rate was 7.4% before the electronic system was used and 6.5% after implementation.

From the Meditech system, the researchers found that although records from the earliest admissions could not be accessed on the electronic prescribing system, 150 patients (who received 2,872 prescriptions) were studied. There were 8.6% prescribing errors before implementation of the system and 8.8% after. The researchers found large differences in how many errors were detected when using the four different methods of measuring errors at Charing Cross Hospital – prospective collection, retrospective review, spontaneous reporting and the trigger tool.

For 93 patients studied at the hospital before electronic prescribing was introduced, there were 1,258 medicines prescribed, and for the 114 patients studied after electronic prescribing came in, there were 1,614 medication orders. Using all of the four methods for measuring error, there were 135 errors detected in total before electronic prescribing, with no cases of harm, and 127 errors after it was introduced. For the errors before electronic prescribing, prospective collection found 48 of the errors (36%), retrospective review found 93 (69%), spontaneous reporting found just one error and the trigger tool found none, but generated many false positives.

Only seven errors were found by both prospective and retrospective means, suggesting that they mainly detect different types of prescribing error. The researchers said that having a ward pharmacist prospectively record the prescribing errors identified during routine prescription monitoring identified only 30% of all prescribing errors. The most productive method of measuring errors appeared to be retrospectively reviewing the medical notes, although this was time consuming.

Understanding the results
When focusing on the qualitative aspect of their study, the researchers found many themes emerged from carrying out observation of staff at hospitals and interviewing them. Several common issues emerged including the need for good training and support as an essential element of successful implementation and the need to convince staff to buy into the concept that this was a worthwhile development. Another issue was that there needed to be an extended
implementation period, resourced to provide support and to help good new practices embed.

When asked, different staff groups generally considered the systems as useable and safer, or potentially safer, in reducing some errors. Nurses, who were the most skeptical at first and found the period of implementation difficult, later agreed with other staff that electronic prescribing should stay and was preferable. Other themes included:

- Emerging change should be expected and managed because electronic prescribing could lead to a reduction in interaction with patients and between other professionals
- Technical systems are never perfect so they should continue to be developed both to improve performance and to allow for changing understanding
- Software should be specified so it is possible to adapt it locally and so that the data held are easily accessible for multiple purposes.

The researchers warned that it would be wrong for people to think that electronic prescribing systems would work in all cases – they have limitations. New errors were introduced as a result of the ServeRx system coming in such as picking the wrong drug from a list of products when prescribing. An accompanying report to this research looked at the Heinrich ratio (which assumes a fixed relationship between non-harm accidents, minor harm and major harm) as a way of predicting harm from medication errors. The researchers said this accompanying report rejected the Heinrich ratio’s validity for medication errors and underlined the need for work to look at the relationship between drug error and harm.

Summary of main findings:

- Using an electronic prescribing and closed-loop system reduced the number of prescribing errors made in a hospital from 3.8% to 2%
- Drug administration errors fell sharply from 7% to 4.3% of drug administrations seen after a closed-loop system with an electronically controlled drug trolley with bar-coded patient identification was implemented
- Staff checked patient identity before administering medicines in 81% of cases after a closed-loop electronic system was introduced, compared with just 17% of cases prior to the new system
- Using a trigger tool identified two out of the four cases of real harm at one of the hospitals, but there were many cases where it identified ‘errors’ incorrectly
- For every 100 prescriptions written in a hospital, around 10 errors will be made, but using electronic prescribing could help avoid two or three of those errors
- Asking a ward pharmacist to prospectively record the prescribing errors identified during routine prescription monitoring identified only 30% of all prescribing errors
- After electronic prescribing was introduced, it was no quicker to access patients’ notes for research purposes nor were all patients’ notes available

Conclusions, recommendations and implications for practice and policy:

- Using a structured framework that captures quantitative and qualitative effects is highly useful for evaluating electronic prescribing
- The effectiveness of electronic prescribing systems should be looked at regularly because they, the human systems around them, and the technology they link into will all continue to develop
- Electronic prescribing may improve patient safety but at the expense of increases in staff time
• There needs to be a systematic evaluation of electronic prescribing systems being trialed at present to provide shared learning nationally

• Decision support in this area should be looked at because there is a danger that staff using electronic prescribing assume that certain issues such as allergy checking and drug to drug interactions have already been done when they may not have been

• Hospitals should set up a patient database for theoretical testing of future electronic prescribing systems before being used with real patients

• There is an urgent need for large scale research to explore the relationship between drug error and harm, its extent in the UK and the cost of that harm.
3.1.3 Can IT solutions help improve patient safety?
Professor Judith Cantrill

Key Messages:
- Clinicians believe that electronic patient record systems can make the prescribing process easier and can standardise prescribing, which is one way of cutting errors.
- An IT system needs to have the backing of the people who will use it and any animosity towards it could mean the system will fail.
- Prescribing errors are far more likely to happen when a patient is being admitted to hospital than at any other stage of the hospital stay.
- Clinicians are nervous about over-reliance on technology – just because a computer says something does not guarantee it is correct.
- Doctors consider pharmacists as the best defence against errors rather than relying on an electronic system.
- Electronic patient record systems are not seen purely as an error reduction strategy for prescribing errors.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:

- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Information technology (IT) is an important tool for improving patient safety and can help in addressing the problem of errors made in hospital prescribing. However, some IT systems are reported to have failed in what they were designed to do and, in fact, caused some errors to happen. Making sure they work and work safely is a priority.

Aims of the Study:
The study’s aim was to look at what effect electronic patient record (EPR) systems have on prescribing errors, when those systems have the aim of improving safety. The main objectives of this study were to:

- develop a workable method for identifying and counting prescribing errors, using retrospective and prospective data collection
- further develop a qualitative case study approach to inform the previous study
• provide initial evidence on whether the above methods are capable of detecting change after the introduction of an electronic patient record system
• provide initial evidence on the scale of such a change, if one is found.

**About the Study:**

The researchers carried out their study at two hospital sites by applying multiple methods, using one hospital for retrospective data collection and the other for prospective data collection methods. They carried out various exercises such as scoping of the prescribing systems used and clinical pharmacy system, interviewing pharmacists to get information on policies and practices, and having a case study using various methods such as documentary analysis, interviews, focus groups and observation.

To test how the electronic patient record system worked at the two hospitals, the researchers used first hand observation, based on an existing method used in previous work, which had investigated the functionality of GP computer systems in terms of ability to assure patient safety. A questionnaire was developed (following input from experts) listing features of a secondary care computer system that would help ensure patient safety. This contained 43 statements illustrated with prescribing scenarios. The researchers also created a secure centralised data collection website, using a ‘trigger tool’ that invited the user to pay additional attention to the possibility of specific types of prescribing error in the particular record under review.

**Practical findings:**

*Retrospective study at first hospital*

At the first hospital, the researchers looked at data for 83 patients from their medical records – 20 patients for 1997-98 and 63 for 2003-04. Collectively they had 1,135 drugs prescribed. For all patients, data were collected for a maximum of 20 days and the researcher assessed each prescription for prescribing errors using standard data sources. They identified 211 errors for 64 patients. Overall, this was 2.5 errors per patient, which meant that 18.2% of all prescriptions had at least one error. They also found that prescriptions that had been given before the patient’s admission, or before the 20-day data collection period, were more likely to have errors than other types of prescription.

*Case study from first hospital*

The data they gathered for looking into the electronic patient record system qualitatively came from interviews with staff members, analysis of documents, and an observation of staff entering data using a pre-prepared form that the researchers had developed. For the interviews at the first hospital, the researchers carried out individual interviews with five pharmacists, one pharmacy technician, one nurse and five doctors and three group interviews were held with a further seven nurses.

Topics discussed included previous experience of evaluating IT systems in healthcare, participants’ expectations of the system before working with it, their experiences with it, and their perceptions about changes in professional role and daily tasks, including risk and risk taking behaviour, since IT system implementation.

This hospital had its electronic patient record system installed in the early 1990s, which allowed electronic prescribing of most drugs for patients during their stay and at discharge.

It had been reconfigured over the years and adapted and the researchers found that although the cost to the hospital and national directives from government level were important, locally detected errors had been the real driving force to configuring the ongoing system.

Clinical pharmacy services at the first hospital were seen as increasingly available over the years. Where possible, pharmacists verified all electronic drug orders that they clinically checked via the electronic patient record system, but a round-the-clock service was not possible.

Staff interviewed said prescribing was a risky activity within care management and that it was
sometimes difficult to keep up because of the amount of change in NHS organisations, in which unpredictability was a given. Almost all people interviewed said relying on technology as a way of reducing errors was risky because technology could fail. Not many of the health care professionals interviewed said they considered that the electronic patient record had a direct influence on patient safety. Instead, the technology was considered as simply making the prescribing process easier with aspects such as drop down menus and the ability to access data from a distant source.

The system did, however, allow for standardisation of prescribing, which was seen to be one way of reducing errors. Doctors felt that, because electronic alerts built into the system as a safety check could be ignored or bypassed, pharmacists were the most useful defence against errors. People interviewed said they appreciated the importance of face to face communication in healthcare – between staff, staff with patients/carers and between primary and acute care – in maintaining safe patient care. Electronic systems could not replace that.

**Prospective study in a heart care unit at second hospital**

At the second hospital, the researchers gathered data for 54 patients from their medical records over six data collection periods in 2005. Collectively, they had 1,279 drugs prescribed. They identified 100 errors for 37 patients. Overall, this was 1.9 errors per patient, which meant that 7.7% of all prescriptions had at least one error. Because this hospital did not have in-patient electronic prescribing at the time of this study, the researchers looked for prescribing errors using two additional sets of data collected:

- data relating to errors detected on all wards was carried out by ward pharmacists on 38 randomly selected days over 18 months
- descriptive data were collected about the errors occurring in discharge prescriptions over four separate, randomly selected, weeks for patients discharged from medical and care of the elderly wards.

For the collection of data relating to errors detected on all wards, the researchers studied 33,012 hand-written prescriptions reviewed for 5,199 patients. There were 3,463 errors (in 10.5% of drugs) identified for 2,040 patients, representing 0.4 errors per patient. The average likelihood of an error being identified on admission was about 14.5%. It was significantly lower at all the other stages of the hospital stay.

**Retrospective study describing errors at second hospital**

The other set of data used by the researchers was about errors happening in discharge prescriptions. Electronic discharge prescriptions for 3,763 drugs were written for 427 patients in the four weeks of data collection. There were 468 errors identified for 234 patients, representing 1.1 errors per patient and, overall, 12.1% of all prescriptions had at least one error.

**Case study from second hospital**

The data the researchers gathered for looking into the electronic patient record system qualitatively here also came from interviews with staff members, analysis of documents, and an observation of staff entering data using a pre-prepared form that the researchers had developed. At the second hospital, interviews were held with three pharmacists, four nurses, six doctors and one focus group with three pharmacists and two pharmacy technicians present. This hospital had its electronic patient record system installed in the early 2000s, which only allowed electronic prescribing of most drugs for patients at the time of discharge and not during their stay.

In-patient prescribing was due to have been piloted at the hospital in 2005, but had been delayed. Nevertheless, the IT department had tested the electronic prescribing system and upgraded and enhanced it. The clinical pharmacy services at the hospital were based on a set of standards that were being revised at the time of this research to ensure they helped to reduce errors.

Staff interviewed said they found the two-hour induction to using the electronic patient record system enough, but more senior doctors were irritated by the system’s inflexibility and felt a back-up paper system was needed because of possible computer crashes. Different staff had different opinions on the efficiency and usefulness of the electronic patient record, the researchers found. Nurses felt the system could convey information quicker, help with nursing assessments, and allow them to spend more time on direct patient care.
Pharmacists welcomed the fact that the system allowed them a complete and up to date record which could improve the quality of patient care. It was a great time saver, they felt, and reduced the potential for transcription errors. Doctors thought the drop-down menus were useful and junior doctors felt it made them more efficient by cutting time they used to spend doing paperwork. It was not, however, a perfect system, and some of the doctors said they would rather rely on a pharmacist to detect whether, for example, a drug was different to the one the patient was normally prescribed – something the electronic system would not pick up on. The pharmacists accepted they had a “safety net” role in detecting prescribing errors made by doctors.

Doctors had some concerns that looking at a patient’s history on computer screen, while useful, could lead to a tendency to be over-reliant on what had been prescribed previously – which could make a previous error worse. Pharmacists said that in the case of the intensive care unit, because so much information was available and necessary for each patient, they still wanted to have a verbal transfer of information even though they had the advantages of an electronic system and paper notes. Another potential source of error identified was when doctors printed off discharge prescriptions well before a patient’s actual discharge, and subsequent changes were made that the pharmacist was unaware of, with the result that wrong prescriptions were made up.

Summary of main findings:

- Pharmacists do not believe that using electronic patient records will affect patient safety, but only that it makes prescribing easier
- Doctors believe pharmacists and not electronic systems are the best defence against errors
- Just under a fifth (18.2%) of all prescriptions at one hospital had at least one error and around 10.5% of all prescriptions at the other hospital
- Errors happened in 12.1% of all electronic discharge prescriptions in one hospital
- Overall, almost half (44.7%) of patients have at least one error identified on their prescribed medication at the time of admission to hospital
- The likelihood that a prescribing error will be spotted is higher when a patient is being admitted to hospital than at any other time during their hospital stay
- Using paper records to gather reliable data on patients is unsound because often they are missing important facts.

Conclusions, recommendations and implications for practice and policy:

- Future research into electronic patient records should combine quantitative and qualitative approaches for fuller and more illuminating findings
- Hospitals should address error producing conditions when designing their staff training and risk management strategies
- Electronic patient record systems should be formally tested locally where they will be used to assess and maximise the potential for preventing errors as well as identifying new types of errors that the system might cause
- Electronic patient record systems can make prescribing easier as prescriptions are legible, complete and can be done remotely with the necessary safeguards, making staff’s job easier
- Some errors are made specifically because of electronic patient record systems, such as prescribers accidentally choosing the wrong drug, dose or formulation because they are unaware of which of the options presented to them was correct.
3.1.4 Ways to reduce drug dose calculation errors in children

Dr Ian Wong

Key Messages:

- The interventions considered to offer the most potential to reduce calculation errors in children’s drug dosing are, electronic prescribing systems, robust double checking procedures, ‘intelligent’ intravenous infusion pumps, and Centralised Intravenous Additive Services (CIVAS), particularly if they could be used in combination

- Hospitals are very aware of the problem of child drug calculation errors and there are many interventions in use in the NHS to tackle this

- There is a real lack of audit, quality and performance data on interventions to measure their impact on reducing medication errors

- The views of staff are important and should be taken into account before implementing any intervention because resistance to change could be a problem.

- NHS organisations should remember that training and staff support is necessary to maintain interventions successfully

- Audits of the effectiveness of interventions should be carried out before and after they are implemented.

Background:

There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government.

A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:

- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Medication errors are the most common type of medical error and potential adverse drug events (side-effects and medication errors) have been shown to be common in children and may be up to three times more so than in adults. Dosing errors are the most common type of medication error in children but there is a scarcity of UK research into child medication errors.
Aims of the Study:
The study aimed to identify interventions that reduce dose calculation errors in newborn infants and children and to evaluate how useful, effective and transferrable they are for the whole NHS.

About the Study:
The researchers used several methods for their research including:
- carrying out a systematic review of existing literature
- surveying neonatal (newborn baby) and paediatric (child) healthcare professionals and UK health information technology (IT) suppliers
- interviewing paediatric healthcare professionals, community pharmacy representatives and carers/patients
- carrying out an observational study of interventions used in clinical practice
- an independent expert panel assessing certain promising interventions.

Practical findings:

Review of research
Firstly, the researchers reviewed existing studies on this subject and initially considered 2,774 articles, of which there were 17 relevant ones.

They found that the most commonly published studies describing interventions to reduce medication errors described forms of electronic prescribing or computerised protocols, followed by Unit Dose Dispensing Systems, where drugs are provided as single doses and dispensed every 24 hours for each patient. Most of these studies were from the US.

Since introducing these interventions, some hospitals claimed significant reductions in medication errors, and some said it had led to such errors stopping completely. It is hard to know how transferable they are to the UK NHS, since the way medicines are managed here is very different to how they are managed in the US.

Other interventions included education/risk management programmes, ‘Smart’ or ‘intelligent’ intravenous pumps – pumps with software to calculate drug infusion rates for individual patients and that alert the user of possible overdose or non-adherence to guidelines – and computerised drug formularies.

Many studies claimed there had been a significant reduction in medication errors due to the interventions, but some of these had consequences such as nursing staff having to spend more time at computer terminals and less time at the bedside, reducing staff to patient ratios.

Survey of NHS staff
The researchers carried out a survey of staff at different organisations asking them if they were aware of any interventions in their institutions aimed at reducing errors in dose calculations in infant and child patients, and to describe them.

The staff surveyed included clinical directors of paediatric services, neonatal (newborn infants) and paediatric pharmacists, and US and European paediatric health professionals and medication errors researchers.

From the 319 overall responses, 148 institutions reported at least one intervention and of these, 126 were from the UK.

Overall, 424 interventions were identified and analysed which showed there were 30 types of intervention reported, grouped under three headings:
- technological interventions such as electronic prescribing, software to help in calculation and dose selection (e.g. in hand held devices), and intelligent infusion pump systems (‘Smart’ pumps)
• healthcare professionals practice interventions such as clinical pharmacy service with pharmacists on the wards, double checking, professional education and feedback of error reports
• others such as written guidelines, support references, a medication nurse, pre-printed prescriptions, forms and labels, and quiet rooms to allow staff to do dose calculations and drug preparation without interruptions.
• The researchers found that electronic prescribing was not the most reported intervention, reflecting that such systems were not yet in wide use in the UK, despite a government drive to promote them.

IT survey
The researchers also carried out a questionnaire survey of 75 health IT companies with systems or software to reduce calculation errors in children’s drug dosing. In all, 41 companies responded and of those, 12 said they had or were about to have interventions aimed at decreasing errors in child dose calculations.

Most of them used simple approaches such as:
• ‘Hypertext Link’ to the drug formulary that allows prescribers to check with the recommended dose
• single default dose per product that helps the prescriber to select the appropriate strength of a medication
• using a computer to run an automatic check of the prescribed dose against a maximum daily dosage for each drug.

For future planned interventions, some companies mentioned automatic dose calculators by using a child’s age and/or weight.

Observing interventions in practice
An expert multidisciplinary panel was brought together including a practicing paediatrician, a paediatric pharmacist, a paediatric nurse, a deputy chief pharmacist, a regulatory authority medical assessor, a senior editor of the British National Formulary for Children and a pharmaceutical industry representative (also a paediatrician).

This panel was asked to select interventions from those identified from the earlier work done by the researchers which would then be observed in practice. The panel members said the five areas they considered a priority were:
• software used to perform calculations
• double checking procedures
• electronic prescribing systems
• clinical pharmacist activity
• ‘Smart’ infusion pumps.

They agreed on 22 interventions suitable for further investigation. These were:
• 3 electronic prescribing systems
• 2 ‘Smart’ infusion pumps
• 3 commercial prescribing packages
• 3 ‘home-grown’ in-house electronic packages
• 3 methods of double checking
• 4 methods of education
• 2 ‘environmental’ such as quiet rooms and employment of a dedicated medicines nurse
• 2 Centralised Intravenous Additive Services (CIVAS) under which a pharmacy provides doses of certain intravenously administered drugs in a ready to administer form.

The researchers carried out interview-based studies with key personnel involved in adopting and using each chosen intervention as well as an observation of the intervention being used in practice. They interviewed senior, middle and low grade managers, doctors, nurses, pharmacists, support staff and carers/patients. A total of 161 people were interviewed face to face and a further three provided written feedback to specific questions.
People using the interventions were observed with their permission and details were recorded. The researchers used a framework that looked at the structure of the intervention in question, the process of using it and the outcomes. Each of these were looked at in terms of how the system technically functioned, the human perspectives and in light of the healthcare service where it operated.

In some cases, the intervention used improved communication between staff, but there were other less welcome consequences such as increased workload and nurses who felt that using electronic prescribing systems meant less time could be spent in direct contact with patients.

Most of the hospitals visited said they had a “gut feeling” that the interventions actually reduced dose calculation errors but only one hospital had evidence to support this.

Other factors were involved and many of the institutions studied operated a no-blame culture which encourages more reporting of errors. This culture could have increased the number of recorded errors rather than any impact from an intervention.

All of the results were presented to the expert panel and ranked in terms of an intervention’s ability to reduce error, transferability, and cost.

They concluded that the top three interventions were CIVAS, robust double checking procedures, and ‘Smart’ intravenous pumps. All three interventions used together were likely, they said, to offer the best chance of an error-proof system for reducing dose calculation errors.

**Economic evaluation**
The expert panel chose CIVAS, double checking procedures, and ‘Smart’ intravenous pumps as the three interventions most suitable for economic analysis. However, because of a lack of data of the impact of the interventions at the various hospitals studied, the researchers and the expert panel agreed that it was not possible to carry out a cost-effective analysis.

They also decided it was impossible to carry out a simulation study for the same reason.

**Summary of main findings:**

- The most common intervention used to reduce errors in calculation of child drug doses is electronic prescribing systems with or without clinical decision support. Most experience of these has been in the US so far although a few centres in the UK are developing them.

- A combination of three interventions – robust double checking procedures, ‘intelligent’ infusion pumps, and CIVAS is likely to reduce most newborn infant and children dose calculation errors.

- There is a lack of data about how clinically effective and cost effective most interventions are.

- The nature of many interventions used in hospitals are different to those that have been studied in previous research so their effectiveness has not been formally evaluated and is uncertain.

- Many IT companies have already begun developing systems to reduce dosing errors in children, such as dose calculators and dose range electronic support modules.

- Although staff are enthusiastic about their interventions, most do not have hard evidence that these have reduced dose calculation errors in children.

- Many interventions have an impact on staff’s workload, sometimes increasing it.
Conclusions, recommendations and implications for practice and policy:

- Pre and post audit is essential to measure the effectiveness of an intervention to help reduce dose calculation errors, using a standardised approach.

- NHS trusts should be encouraged to publicly disseminate information (positive and negative) on interventions tried and tested for the benefit of the whole NHS.

- More research is needed to support and improve double checking practices, which were identified in this study as theoretically one of the most promising interventions to reduce drug errors.

- Research is needed to establish whether or not new types of error will happen as a result of introducing ‘intelligent’ infusion pump and electronic prescribing systems across all UK hospitals.

- There is a need to develop a standardised approach to measuring errors so that evaluation and comparison of interventions is possible.

- High quality studies to examine the effectiveness of the specific interventions of ‘Smart’ pumps, double checking and CIVAS are worthwhile.

- Future research should investigate the cost of child medication errors and cost effectiveness of any interventions implemented to prevent them.
Chapter 4 – Qualitative/ Exploring Wider Issues

4.1 Introduction by

Professor Charles Vincent
Professor of Clinical Safety Research, Imperial College London

Patient safety is a tough problem; tough in cultural, technical, clinical, and psychological terms and because of its massive scale and heterogeneity. Healthcare encompasses the mostly routine, but sometimes highly unpredictable and hazardous world of surgery; primary care, where patients may have relationships with their doctors over many years; some highly organized and ultra safe processes, such as the management of blood products, and the inherently unpredictable, constantly changing environment of emergency medicine. In all these arenas both error and harm to patients are real possibilities and frequent actualities, though the nature of the harm, its causes, consequences and likely methods of prevention will differ widely according to context. Analyses of these incidents showed us the range of potential influences and, by implication, the range of factors that needed to be addressed.

The studies in this section have, on the face of it, very little in common beyond the innovative and thoughtful approaches taken by the research groups. Together however these studies show us the range of factors that patient safety has to address and the challenges involved. They concern the design of systems, methods of assessing hazard, modes of learning, the challenges of education and training, initiatives to reduce harm and reflections and guidance on handling the aftermath for patients, families and staff. Understanding safety truly does lead us into considering all the facets of the healthcare system.

Reviewing the various contributions and reflecting on the evolution of patient safety over the past fifteen years we can be encouraged by the progress made in research terms, but the studies in this section show us that less progress has been made on the ground. The analysis of incidents in healthcare has been reasonably well understood for a decade, but in practice analyses are often superficial and feedback erratic. There is a wealth of educational material available, as ten minutes on Amazon will tell you, but many training institutions are struggling with patient safety. Most disturbing perhaps is the lack of support for patient, families and the clinical staff and managers who suffer the aftermath of the incidents we are all concerned to prevent. We have known for over ten years that injured patients, unless burdened by caring for the seriously handicapped, are generally not motivated by a wish for compensation but by the basic human need for recognition, apology, accountability and the wish that no one else suffer in the same way. Healthcare organisations, dedicated to caring and healing, still struggle to recognise these basic truths. In this area, as in others, we still have a long way to go. All the studies however, have identified beacons of excellence and real innovation which show us what can be achieved. The Patient Safety Research Programme supported and inspired us all towards a better understanding of how to enhance safety; it is clear that the task for the next few years is the translation and implementation of that knowledge beyond the research community.
4.1.1 Communication with patients after errors  
Dr Lesley Fallowfield

**Key Messages:**
- There is currently no generally accepted ideal way of handling communication with patients after a medical error has happened.
- Poor communication about an adverse event may be why patients decide to sue doctors or hospitals while good communication can reduce the likelihood of complaints and litigation.
- Doctors have to be better equipped with skills to deal with the emotionally charged discussion that surrounds admission of error.
- There is no universal formula for communication about adverse events because they are dependent on circumstances, the event, suspected cause(s), outcome, personnel involved and the needs and preferences of the patient and/or relatives.
- Medical errors rarely lead to litigation but concealing them and then being found out later does increase the likelihood of being sued.
- Professional organisations, bodies and associations should try to change the culture of infallibility and competitiveness within the medical profession to encourage more open discussion about errors.
- NHS organisations need to take a leading role in patient safety with a collaborative agreed strategy and ensure they are supportive of clinicians in their efforts to be open and sensitive with patients if an adverse event has occurred.

**Background:**
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them.

Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government.

A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

The origins of errors in healthcare can often lie in poor communication which is considered to be a core clinical skill and which also plays a part in making mistakes worse or improving them.

Good communication can increase patient satisfaction, enhance the professional and personal wellbeing of healthcare professionals and reduce the likelihood of complaints and litigation. Similarly, poor communication over an adverse event may cause patients to sue doctors or hospitals, but revealing errors can also lead patients to take action when, prior to disclosure, they were unaware an adverse event had happened.
Aims of the Study:
The study was designed to come up with basic principles to guide communication with patients and their families following a medical error and to help prioritise what needs to be done in future relevant research.

About the Study:
The researchers carried out an extensive review of existing research and literature up to 2003 on the subject using research databases and also accessed websites of relevant organisations for policy documents. They also studied work happening at the time such as a major initiative in Australia called the National Open Disclosure Project designed to improve the practice of open disclosure by giving healthcare professionals practical tools to adopt good practices.

Practical findings:
The researchers started from the point of view that good communication with patients and between healthcare staff is important at all times, whether or not there has been an error made, but it is not and cannot be a precise science.

Effective dialogue that is tailored to an individual patient's needs can help prevent some of the errors, complications and distress that happen in hospitals.

Good communication can:
- help patients understand complex information
- make appropriate choices between treatment options
- be more aware of the side-effects and potential hazards of some procedures
- be clearer about likely therapeutic gains and the purpose of treatments
- help patients keep to drug regimes and diets.

At the time the paper was published, the researchers said there was no clear consensus about how best to handle communication with patients about medical errors once they have happened.

Definitions and categorizing
Informing patients about an adverse event and apologising if an error has been made is considered to be the ethical approach in healthcare, say the researchers.

However, the reality is that it is often hard to know precisely whether an error happened and whether any injury or harm was a direct result of the error and who or what factors were responsible.

It is therefore important that staff remember they may have to use different ways of categorising adverse patient incidents – such as by cause, type of error, outcome or type of setting of staff member involved – when developing a framework about how to communicate with patients after an incident.

The factors leading up to an adverse event and the type of setting or personnel involved are relevant, say the researchers, so should be considered when deciding who should be involved in the process of telling patients about an incident.

The researchers found different definitions of ‘error’ and ‘mistake’ used in other pieces of research and decided to use the NPSA definitions of ‘adverse patient incident’, ‘harm’, ‘adverse event’ and ‘near miss’ to describe events according to outcome.

‘Adverse patient incident’ is defined as any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage.

‘Harm’ is any injury (physical or psychological), disease, suffering or death. Incidents that lead to harm are referred to as ‘adverse events’ and those that did not lead to harm, but could have, are referred to as ‘near misses’. Precise definitions of ‘error’ or ‘mistake’ are not given by the NPSA, but
the paper uses the term ‘error’ to refer to the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

**Practice of disclosure**
Existing research has found that clinicians tend to be less than forthright with patients about adverse events.

Higher numbers of doctors, in theory, do disclose and admit their errors, shown in surveys that used hypothetical scenarios, but that proportion is lower in real life situations of actual experiences.

The researchers say the willingness of a doctor to disclose the error of another treating doctor may be lower than the willingness to admit their own errors. Willingness to admit errors could also be dependent on the degree of harm or injury resulting from an error.

**Reasons for disclosure**
The researchers found many studies which showed that the majority of the public and doctors believe patients and or their families should be told about errors.

However, larger proportions of the public than doctors felt they should be told if errors or complications happened during treatment.

Generally, it is considered ethically appropriate to disclose errors, say the researchers. Overall, the benefits of disclosure outweigh the negative consequences and doctor patient relationship and trust can be strengthened by honesty.

It is commonly believed that disclosing errors is risky and increases the likelihood of being sued, but the researchers found that this was not supported by recent data. Medical errors rarely lead to litigation.

Liability may be imposed on a doctor because of their failure to reveal a medical error, especially if it is uncovered later.

**Barriers to disclosure**
Doctors face conflicting moral dilemmas when deciding whether to reveal their own or a colleague’s error, such as their personal values; professional obligation to prevent a recurrence of the error; patient’s right to know the truth; and positive or negative effects on the doctor-patient relationship.

The current legal system does not encourage health professionals to be open after an adverse event, say the researchers, but legal considerations should not determine whether or not errors are reported. Another barrier is the lack of clear direction, commitment and support from an organization, institution or hospital trust in some cases, says the paper.

Any clinician attempting to be open and sensitive will be undermined if there is not a collaborative approach between clinicians and between clinicians and management with a basic strategy agreed by the hospital trust board. The researchers say there are useful tools that have already been produced including those in the Australian Open Disclosure Project that could be adapted and used in the UK. Systems breakdowns are a key cause of errors, as this influences communication about errors. Many errors are not reported because health professionals fear they will be punished by disciplinary systems. Cultural issues are another barrier, say the researchers, as the prevailing culture within the medical profession, e.g. infallibility and competitiveness, hamper open discussion about errors.

Professional organisations, societies, groups and associations can help in this area by trying to change that culture to encourage identification and prevention of errors.

The researchers found there is a real lack of Professional organisations, societies, groups and associations can help in this area by trying to change that culture to encourage identification and prevention of errors. The researchers found there is a real lack of training programmes for risk management and communication which means health professionals often do not have crucial communication skills to help them handle adverse events.
**Effective communication**

The researchers propose some of the skills to achieve effective communication in the paper, derived from various sources.

Before a meeting with a patient and/or their carer/family, the doctor involved and their organisation should ensure they have all the relevant facts ready as well as any other important information about the patient and arrange for the meeting to happen in a comfortable private environment.

During meetings, there should be:
- a clear description of the adverse event and probable outcome
- explanation of what happened
- expression of sorrow or regret and a genuine apology
- revision to the care plan, rehabilitation
- information about measures being taken to prevent a similar occurrence opportunity for further discussion
- discussion of procedures for compensation
- emotional support
- details of a full inquiry

**Training**

Many studies considered for this research show that clinicians feel they have not been adequately prepared or trained for discussing any bad, sad or difficult news with patients.

At the time of this research, it was clear that clinicians needed far more training programmes to help them improve communication despite the fact that there were some training videos and workshops in existence to help and promote open disclosure.

A training programme to help professionals with disclosure about medical error is proposed and described in the paper and is based on a communication skills model shown to be effective for senior doctors in cancer medicine.

**Support for patients**

Support for patients after an adverse event should be an integrated part of care, says the paper, and this support can include information about disability benefits, talking to others who have had similar experience, factual information, or it can involve more formal psychological counselling.

More attention should be paid to understanding patients’ psychological and social problems following an adverse event as these are often missed by the professionals involved in their care.

The main forms of trauma experienced by patients harmed by treatment are chronic pain, bereavement and loss, depression and anxiety. A patient might want to talk to an independent counsellor or professional after an adverse event.

Studies have found that most victims of medical accidents are more concerned with accountability rather than compensation for an incident. Many want a face to face apology from the person responsible.

**Support for doctors**

Support for doctors is another important consideration, say the researchers, because they are often deeply affected emotionally and psychologically if they make an error or are involved in the care of someone harmed by an adverse event. Just discussing an adverse event with a patient can cause emotional distress for the doctor who wants emotional support and professional reaffirmation after making an error, says the paper. They are, however, sometimes reluctant to ask for support which can come in many forms including a ‘quiet word in the corridor’ or the offer of extended psychotherapy.

The researchers say that there is a demand for legal advice and training within the hospital setting. Education could be given about medical law and the legal process in teaching sessions or seminars by hospital solicitors or doctors who act as expert witnesses in court.
This could help doctors to understand the legal process and alleviate the stress and fears associated with litigation.

**Summary of main findings:**
- NHS staff often do not have crucial communication skills to help them handle adverse events and this is something they receive little or no training for.
- There is no clear consensus about the best way to handle communication with patients about medical errors once they have happened.
- Doctors’ culture of competitiveness, the fear of damage to reputation and loss of respect from peers prevents them from attempting to have better communication with patients when something goes wrong.
- Most victims of medical accidents are more interested in accountability rather than compensation for an incident and many want a face to face apology from the person responsible.
- Doctors want emotional support and professional reaffirmation after making an error, but can be slow to seek such support.
- Clinicians have very different styles and skills of communication and their ability is not always related to how much experience they have.

**Conclusions, recommendations and implications for practice and policy:**
- Research in this field is difficult because of the sensitivities that surround discussion about and acknowledgement of error, and participants may be hard to find from doctors and patients that are already involved in litigation.
- Despite the sensitive nature of this subject, there is a need for more UK-based practical research about patient and doctor preferences around communication issues and behaviour following an adverse event.
- There is an urgent need for a thorough scoping exercise in the UK in order to identify examples of good practice and initiatives.
- Future research could look into the impact of the outcome of an adverse event on communication preferences and whether patients would rather not have known about a mistake.
- Research could also be carried out into whether there are any special needs or preferences of particular groups with regard to communication after an adverse event, e.g. for older people.
- Investment is needed to offer legal advice and training within the hospital setting to help some doctors understand the legal process and reduce the stress and fears associated with litigation.
- Opinions from trusts, the BMA, the Royal Colleges, medical defence bodies and groups representing consumers should be sought to see if they are willing to adopt a more open disclosure policy in the UK.
4.1.2 Diagnosis of difficult cases in primary care  
Dr Olga Kostopoulou

Key Messages:
• The study found no evidence that doctors with more experience make fewer misdiagnoses of difficult cases – this is in line with other research findings that experience increases confidence but not necessarily accuracy

• Gathering large amounts of information during the consultation does not guarantee accuracy – it is the ‘right’ information that is important i.e. information that has diagnostic value

• Making a correct diagnosis means a patient is far more likely to have their case appropriately managed by the doctor and this includes appropriate referral decisions

• The importance of diagnosis in general practice needs to be re-emphasised, supported and developed

• The potential for using IT in gathering and presenting information during the diagnostic process should be explored

• Issuing written reminders and developing guidelines to plug ‘gaps’ in GPs’ knowledge is not enough to deal with diagnostic error – a more comprehensive strategy needs to be developed involving clinicians, patients, targeted training, and electronic health records with integrated diagnostic support.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the Government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS. It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year. As well as setting up the NPSA in 2001, the Government launched a large scale research programme to:
• explore the size and nature of the problem
• understand the factors causing harm
• develop interventions to reduce errors
• assess how effective the attempts to reduce errors have been
• implement ways of guaranteeing change in people and organisations.

General Practitioners (GPs) are the first point of contact in the NHS for the majority of patients so they play a crucial part in prompt and accurate diagnosis, which is central to maintaining patient safety. Diagnosis, however, can be difficult in some cases and although clinicians rarely report their own diagnostic errors, such errors account for two thirds of litigation claims against GPs. Few studies so far have studied the role of information gathering using realistic diagnostic problems and evidence-based criteria for assessing performance.

Aims of the Study:
The overall objectives of the study were to construct a range of clinical scenarios and present them to GPs to diagnose and manage in order to investigate the relationship between information gathering and diagnostic accuracy; diagnostic accuracy and appropriateness of patient management; and changes in performance with clinical experience. Its main aims were to:
• identify types of diagnostic difficulty commonly encountered in primary care
• identify predictors of diagnostic accuracy
• make recommendations for improving and supporting diagnosis in primary care.

About the Study:
The researchers reviewed litigation data, papers that reported conditions that get misdiagnosed and reasons for diagnostic errors in primary care, and interviewed GPs with a research interest in diagnostic error, evidence-based practice and quality of care. They thus compiled a set of 10 features of diagnostic difficulty. Using these features, they constructed seven clinical scenarios that were sufficiently complex to allow them to investigate instances of misdiagnoses and potential performance differences between GPs. Furthermore, the scenarios involved diseases that were not trivial, to investigate the importance of diagnostic accuracy for appropriate management. Though the diseases involved were not ‘routine’ for primary care, one only of them was truly rare.

Practical findings:
Common diagnostic problems
To prepare for their study, the researchers wanted to establish what constitutes diagnostic difficulty in primary care. For this purpose, they used a variety of sources to identify conditions and presentations that get misdiagnosed: they examined existing reviews of litigation data, conducted a systematic review of existing research, and interviewed GPs. From the litigation data, they examined an existing review of 1,000 claims made against GPs and another, more detailed, review of a subset of these claims. Some causal factors relating to clinicians’ thinking processes (‘cognitive’ factors) emerged from these:
• not investigating uncommon diseases, if some of the symptoms can be explained by more common diseases
• failing to give sufficient weight to risk factors, failing to gather diagnostic information and ignoring important clinical signs
• giving too much weight to normal test results
• failing to consider a rare disease.

From the systematic review of existing research, the team found 21 relevant research papers that they included in the review. These referred to a range of conditions, which the investigators classified according to the reasons for the delay in their diagnosis as: atypical presentations; non-specific presentations; very rare conditions; co-morbidity (presence of more than one disease); and visual symptoms and signs that were missed. By interviewing seven GPs with an interest in diagnostic error, the researchers identified further conditions and presentations that were seen as difficult to diagnose. Taking all three sources together, several more or less rare diseases were identified as potential areas for misdiagnosis for example various cancers, meningitis and childhood diabetes. Cancers were most frequently associated with missed or delayed diagnosis in all three sources of evidence.

More common conditions, however, were also linked to diagnostic delay, such as heart disease, dementia, and iron deficiency anaemia. Visual signs were sometimes missed such as melanomas and septicaemic rashes because the doctor failed to detect them or once they detected them, they did not recognise and interpret them correctly. The researchers found that listing diseases that get misdiagnosed is probably not as useful an approach as identifying types of presentation that are difficult to diagnose and increase the likelihood of error.

From the three sources combined, the researchers identified 10 features that make a case difficult and increase the chance that an error will be made.
• single, non-specific symptom at initial presentation
• multiple non-specific symptoms that do not make a pattern
• obvious, but not necessarily the correct cause
• uncommon critical cues (diagnostic information) or cue-disease associations
• atypical presentations
• critical cue that is necessary for diagnosis
• higher prevalence of the main competing diagnosis
• rare disease
• causally interacting co-existing diseases with partially overlapping features
• causally independent co-existing diseases with partially overlapping features.

Misdiagnoses, they found, were mostly due to combinations of features, such as a rare disease with a non-specific presentation.

Building the scenarios
The researchers designed seven scenarios that contained combinations of these features. In brief, the scenarios were:

• pyrexial child – a toddler with fever presenting three times to the GP
• dyspnoea (difficulty in breathing) – 68-year-old man who is a smoker with dyspnoea
• abdominal pain – young woman with abdominal pain for the past three months
• chest pain – 60-year-old man with chest pain, first felt while lifting a washing machine
• dyspnoea 2 – elderly patient with chronic obstructive pulmonary disease (COPD) with episodes of dyspnoea increasing in frequency
• headache – 69-year-old woman with headaches and other non-specific symptoms
• fatigue – 52-year old man on antidepressants with fatigue and dry mouth.

These were designed to be detailed and realistic patient scenarios, representative of the more difficult spectrum of what GPs see in their dealings with patients. The scenarios were designed to contain both relevant and irrelevant information (cues), as happens in real-life consultations. Certain cues were considered ‘critical’, if they provided evidence for one or more of the relevant diagnostic possibilities in each scenario. The researchers reviewed the evidence and also used the estimates of multiple experts to determine which cues were ‘critical’ in each scenario.

Participants, after being presented with the patient description and presenting complaint, would be able to request further information in order to diagnose and manage the patient. The scenarios were extensively tested before the official data collection, to ensure that they contained all the information necessary for a GP to arrive at a diagnosis, but also, other information that a GP might want to ask a patient, e.g. occupation, home and social life, etc. All scenarios were diagnosable and were repeatedly checked for consistency and plausibility. Finally, the study was piloted in its entirety (diagnosis of all 7 scenarios followed by interviewing) with six GPs.

Recruiting participants and data collection
All GPs from Birmingham and Solihull were invited to take part in the study (778) and, of those, 201 responded and 130 wished to participate. From them, the researchers recruited 84 doctors: 21 GP registrars, 21 GPs with one to three years in General Practice, and 42 GPs with more than 10 years in General Practice, and of those, half were GP trainers and half were not.

Data collection took place at the participant’s home or practice, or at the University. The scenarios were presented on a computer screen. Each time a participant asked for a piece of information, this request and its timing were logged by the computer. The answer to the requests for information was presented on the computer screen.

No time limits were imposed on each scenario but participants were allocated 1.5 hours for completing all 7 scenarios. This included reading of study-related information, obtaining written consent, and practice on a training scenario at the start of the session.

No feedback was provided to the participants about their accuracy at that stage. Following the diagnosis of all seven scenarios, the researchers selected three scenarios and interviewed participants using ‘stimulated recall’.

These were scenarios that the participants had misdiagnosed (but did not know this). They were shown a computer record of their information requests and were asked to recall and explain their thinking. GP performance was measured in a number of ways: number of cues requested (total, critical, non-critical), the time taken to diagnose, diagnostic accuracy (i.e. whether the correct diagnosis was included in the final list of differential diagnoses), and appropriateness of management.
Results across scenarios
The researchers found that misdiagnosis happened 58% of the time (ranging from 43% to 75% depending on scenario). Only one participant diagnosed all seven problems correctly, which suggested that they were indeed difficult. There was a clear relation between the number of critical cues requested and diagnostic accuracy – more critical cues led to more accurate diagnoses. Asking for more cues overall did not relate to accuracy.

Experience did not have a statistically significant impact on diagnostic accuracy. More experienced GPs did not gather more critical cues than less experienced GPs but gathered fewer cues overall, which meant that they were more efficient. The doctors made an appropriate management decision 52% of the time. Most incorrect diagnoses (78%) were followed by inappropriate management, and most correct diagnoses (92%) by appropriate management. This meant that considering the correct diagnosis as a possibility at the end of the consultation determined appropriate management of the patient’s problem, including appropriate referral.

Results by scenario
By analysing the ‘stimulated recall’ interviews of GPs on scenarios that they had misdiagnosed, the researchers tried to understand why the diagnoses had been missed and to derive commonalities across scenarios. Detailed analysis of the ‘stimulated recall’ protocols for individual scenarios showed that the most common cause of misdiagnosing the scenarios was that the correct diagnosis had not been considered at all.

In the absence of a correct diagnostic hypothesis, doctors tried to explain away evidence that did not fit their diagnosis or diminish its importance. Seeing the scenarios again during ‘stimulated recall’ did not result in GPs changing their initial (incorrect) diagnoses, since they were not informed about their accuracy.

Summary of main findings:
- Misdiagnosis of what were difficult cases happened 58% of the time with the average rate of misdiagnosis ranging from 43% to 75% amongst doctors
- Requesting diagnostic information depends on having appropriate diagnostic hypotheses in mind
- If the correct diagnosis is not being considered, doctors will try to explain away evidence that does not fit their diagnosis or diminish its importance
- There is no evidence that GPs with more years in practice are more accurate when diagnosing difficult cases than less experienced GPs
- Appropriate management strongly depends on diagnostic accuracy
- Participating doctors managed around half of all cases appropriately
- Seeing the scenarios again did not result in GPs changing their initial diagnoses, since they did not know that they were incorrect.

Conclusions, recommendations and implications for practice and policy:
- Future attempts to improve diagnostic accuracy should concentrate on supporting clinicians to develop appropriate diagnostic hypotheses, ask for critical information, and deal appropriately with information that does not fit their working diagnosis
- The more diagnostic information GPs request, the more likely they are to diagnose difficult cases accurately
- This could be done through the development of appropriate training tools, as well as computerised diagnostic support in clinical practice. It is essential that computerised diagnostic support interfaces with the electronic Health Record
• The conditions highlighted in the scenarios should be prioritised for the development of clinical guidelines (as has already been done for Coeliac disease)

• Because seeing the scenarios again during 'stimulated recall' did not result in GPs changing their initial (incorrect) diagnoses, this suggests that feedback is necessary for reflection, learning and improvement

• Future research could study the diagnostic process in detail and identify points where decision support could be usefully provided in order to support diagnosis in primary care
4.1.3 Feedback from reporting patient safety incidents – are NHS trusts learning lessons?
Professor Louise Wallace

Key Messages:

- There is too much focus on reporting of adverse clinical incidents and not enough on learning lessons from those incidents to prevent them happening again.
- There is a conceptual framework (SAIFIR) that can be used to test the key features of local systems.
- A tenth of NHS trusts give no information back about the outcome of investigating an adverse incident to the people who reported the incident.
- Trusts should work harder to integrate local and national risk information, sharing solutions, implementing recommended changes and promoting a safety culture.
- Trusts should consider reviewing their staff newsletters to make them more effective and consider making changes such as allowing staff to feedback about feedback.
- A common framework for safety feedback processes that integrates local and national level systems could help the ability to learn from failures at service level.
- Managers and staff are expected to implement changes that have been recommended following an incident, but there are no formal systems to monitor how those changes are going.

Background:

There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:

- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

Clinical incident reporting systems in the NHS are central to measuring patient safety in NHS organisations and feed into the national system known as the National Reporting and Learning System (NRLS) set up by the NPSA.

Much effort has gone into promoting safety through learning from reported adverse events, but the focus so far in other research has been more on methods of reporting and encouraging reporting rather than how to learn from incidents and change practice.
Aims of the Study:
The study’s overall aim was to look at potentially effective ways of providing useful feedback from incident reporting systems in the NHS.

Its specific aims were to:
- establish the different kinds of feedback systems used in healthcare and other sectors
- look at how these feedback systems might be affected by the quality and comprehensiveness of incident reporting systems
- study how effective these feedback systems seemed to be in communication and creating safer systems after a patient safety incident
- examine how effective these mechanisms were on culture and the willingness of staff to report incidents in future.

About the Study:
The researchers used several methods for their research including:
- carrying out a systematic review of existing relevant research worldwide
- studying the most suitable pieces of research in-depth
- interviewing healthcare and non-healthcare industry experts
- surveying all NHS trusts in England and Wales
- investigating case studies of good practice, including the use of safety newsletters and PDA based mobile incident reporting and feedback
- holding an expert’s workshop made up of safety experts from several industries, Royal Colleges, healthcare managers and clinicians
- developing a framework to help develop feedback processes in health care.

Practical findings:
The researchers began their work from the basis that existing clinical incident reporting systems in the NHS take a long time to feed back information and recommendations from the analysis of failures.

Within current systems, there is also little or no systematic follow-up of recommendations proposed to prevent recurrence of specific failures.

A general lack of clarity about priorities for improvement and a lack of effort to develop solutions to prevent specific adverse events recurring are additional problems.

Review of research
Firstly, the researchers reviewed existing studies on this subject worldwide and initially considered 2,002 potentially relevant articles, of which 193 were chosen and their data looked at.

From those, they selected 29 articles that referred to 23 case reports of healthcare incident reporting feedback systems to study in-depth.

To help with this process, the researchers carried out 18 interviews with healthcare and non-healthcare industry experts to discuss safety in health care and high risk industries such as rail, mining, maritime, nuclear power and aviation industries.

They also studied relevant published policy within healthcare including guidance from the Department of Health, NPSA and NHS Litigation Authority, and Australian and North American equivalents.

From taking all of these into account, the researchers developed a theoretical framework called the Safety Action and Information Feedback from Incident Reporting (SAIFIR) framework.

The SAIFIR framework provided a model of the safety feedback process for incident reporting based upon the best practices identified from the researchers’ review and tested against expert opinion in
healthcare and non healthcare industries.

This tool was used to identify specific actions taken to improve the safety of work systems and to identify broad dissemination of information to raise general awareness of current risks to the safety of operations.

Within this tool, the researchers categorised five different modes of action and information feedback:

- Mode A was immediate feedback and acknowledgement to the person reporting an incident or people in the affected service and this was called “bounce-back information”
- Mode B was aimed at “rapid response actions” such as measures taken against immediate and serious threats to safety
- Mode C was the dissemination of “risk awareness information” on current system vulnerabilities from the analysis of incident reports in the form of safety newsletters
- Mode D was feedback information that “informs staff of action taken” including telling the person who reported the incident in the first place
- Mode E was “systems improvement actions” including specific action plans for improvements to work systems that addressed problems identified previously.

The researchers surveyed the 23 cases of healthcare incident reporting feedback systems they had found from their review of existing research to see which of the five feedback modes had been used.

They found that all systems had used feedback mode E, which allowed specific actions to be taken for improving safety of care delivery processes and most had used mode C, meaning they had used a form of safety newsletter.

Fewer (70%) had used mode B, meaning having employed rapid response actions.

Of the 23 cases, 13 had used four out of the five feedback modes and just four cases had used all of the feedback modes.

The least used feedback mode was mode A (bounce-back information) and only 39% of the cases looked at had employed this mode, showing a lack of capability or willingness to report back to the individual who first reported an incident.

The findings were presented to a gathering of 71 people at an expert workshop organised by the researchers. These experts included NHS risk management managers, clinicians, representatives of professional healthcare staff, regulators, and experts from other high risk industries such as the aviation and nuclear industries.

The people attending agreed that developing effective safety feedback processes for incident monitoring was a significant challenge for NHS trusts because of the high volume of reports received at the local organisation level, especially in hospital settings.

Safety feedback, currently in the NHS, was given on an ad-hoc basis, they agreed, and there was more focus on reporting mechanisms rather than on feedback, which was sometimes just an afterthought.

They concluded that reporting rates of adverse incidents were limited in their ability to give a true picture of safety at a particular NHS organisation and were, at best, an indicator of the openness of the reporting culture that existed at a trust. This event helped to refine the SAIFIR model.

Survey of NHS trusts
The researchers set out to survey all 607 NHS trusts in England and Wales at the time this study was carried out, about their risk reporting systems. They got a 57.8% response rate from the trusts’
risk management leads.

Their work was consistent with the key findings of two surveys confined to provider trusts in England carried out around the same time by the National Audit Office. The aims of the researcher’s own survey were to understand:

- how trusts were developing a learning culture
- the development of reporting systems
- the analysis and use of information from incidents, and the place of incident investigation in this process
- how solutions were formulated
- how changes were implemented
- the use of feedback and methods of dissemination within and between local organisations.

They found that the majority of trusts were reporting externally, but at least a third of them received no feedback from their strategic health authority/region.

Trust-wide incident reporting systems were confidential rather than anonymous, so that feedback was not excluded. Analysis of incidents was confined to actual incidents in a third of trusts, which suggested that near misses were either not being reported in these trusts or were being ignored.

How many reported incidents were actually investigated varied considerably from trust to trust and the quality of reports was also variable.

Systems for directly monitoring the impact of recommendations for action following adverse incidents did not exist in around a quarter of trusts.

Overall, the researchers found there was evidence within trusts that staff who reported incidents were not routinely thanked, acknowledged, nor informed of progress, although most were informed of the outcome of any investigation, via a formal report or less often, a personal letter.

Patients were generally informed at the start and end of the process, but this was most often in the context of complaint procedures.

**Using the SAIFIR model**

The researchers used their SAIFIR feedback model on the data they had from the NHS trusts survey.

They found that the risk reporting and feedback systems of the NHS trusts surveyed were highly variable in terms of coverage of reporting and feedback.

Mode A feedback – acknowledgement to the person reporting an incident – was only given by a third of trusts while the Mode B “rapid response action” was not given by any trusts.

The Mode C dissemination of risk awareness information was practiced in all trusts, mainly by newsletters, group meetings and training.

Only two thirds of trusts used the Mode D feedback whereby they informed staff of actions taken, in particular informing the person who reported an incident in the first place. However, a tenth of trusts gave no outcome information to staff routinely.

Around two thirds of trusts used Mode E feedback of improvements in work systems with action taken, but 25% had no systems for monitoring the impact of this action, and 27% of risk management leads responding said they believed it was not acted upon.

The survey results also showed there was considerable progress to be made in most trusts, particularly in integrating sources of risk information, sharing of solutions in changing working practices within and between trusts, implementing and monitoring recommendations, and promoting a safety culture with visible senior leadership.
When the results from the survey were presented to the participants at the expert workshop, this helped them to choose and target in-depth case studies of aspects of feedback in NHS trusts.

**Case studies**
The final stage of this overall study was to examine in detail examples of good, or unsuccessful, attempts to develop effective feedback systems in NHS trusts.

Four cases studies were chosen and the first looked at a NHS trust’s incident reporting system and the way it gave feedback to the person reporting an incident. The other three case studies focused on the use of patient safety newsletters.

The first case study at a large teaching hospital NHS trust dealt with developing a mobile electronic device for clinical risk reporting that included feedback to the person reporting an incident. The researchers either interviewed or held focus group meetings with 23 staff at the hospital.

They found that almost all the staff reported clinical adverse events with a varying frequency but had different opinions as to how much feedback they received. The researchers found that immediate feedback would be welcomed and could potentially be supported by e-working technology for both reporting and feedback.

For another case study, the researchers asked all of England and Wales’ NHS trusts for a copy of their patient safety newsletter. They received 90 responses and after analysing them, they found there was great variation in practice, with few making use of basic design features to make them attractive to readers.

Overall, the case studies showed that although there was enthusiasm for risk reporting, there was scepticism about the importance and relevance of it. The researchers concluded that the credibility and relevance of the information given in newsletters was crucial in helping to motivate more people to report incidents and to encourage safer practice. That effort would also be helped by more senior staff endorsing the reporting systems and giving more positive recognition to staff involved in risk reporting and learning activities.

**Summary of main findings:**
- Risk reporting and feedback systems across different NHS hospitals are highly variable in terms of what they cover and feedback
- Only a third of NHS trusts give formal acknowledgement of an incident to the person reporting it immediately and around 12% give no feedback to staff from incidents reported
- No trust gives advice on immediate action that should be taken following an adverse incident
- All NHS trusts disseminate risk awareness information through newsletters, meetings and training
- Two thirds of trusts get back at some point to the people who reported adverse incidents to tell them how the issue is being handled
- A quarter of trusts have no system for monitoring the impact of adverse incidents being reported
- A third of trusts get no feedback from their strategic health authority/region after they give information on adverse incidents
- Patients are involved in incident investigations only when these are investigated as complaints.
Conclusions, recommendations and implications for practice and policy:

- Staff need to be encouraged to report incidents and get immediate acknowledgement and thanks when they do to show that reporting is taken seriously and will result in positive change.

- There should be a simplification of the current system of multiple reporting and feedback channels within NHS organisations and external agencies.

- NHS organisations should tailor their safety feedback so it is flexible in content, mode of delivery and suitable for a target audience, to ensure it is absorbed more easily.

- Information fed back to front line staff (in multiple methods) must include examples of changes resulting from the investigation of reported incidents and their impact upon safety, if future reporting is to be encouraged.

- Research should examine how mobile technology can make reporting and feedback easier and more easily targeted on those who need to take action.

- NHS organisations should use normal methods of communication, such as e-mail, handovers between staff and team briefings, as well as newsletters to feedback on safety issues.

- Organisations should audit the effect of feedback and ensure lessons are learnt and seen to be learnt to ensure staff can see that their efforts to improve safety by reporting and investigating incidents actually improves patient safety.

Further information:


4.1.4 Early education for health professionals on patient safety
Dr Pauline Pearson

Key Messages:
- Lecturers and healthcare students believe that patient safety is not a separate topic as such but something that underpins everything they do in their work or teaching
- Academics are willing to take on board the drive to improve patient safety and are incorporating it into their courses
- Practice educators are important role models for safe practice
- Students need help to feel more confident to challenge unsafe practice in other staff
- Healthcare students need to look more explicitly at why practice breaks down and the circumstances in which it does so
- Innovative approaches are needed to make patient safety issues ‘real’ for students
- Healthcare students view patient safety positively and see it as learning to deal with real issues for real patients.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the Government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year.

As well as setting up the NPSA in 2001, the Government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective the attempts to reduce errors have been
- implement ways of guaranteeing change in people and organisations.

Patient safety is a consideration for clinicians while they are at college or university for pre or post-registration education and training. There are obvious ways of intervening at this stage of their professional lives to assure patient safety in health care practice.

However, there is little evidence, so far, of the ways in which learning about patient safety can be effectively incorporated within the health care curriculum.

Aims of the Study:
The study’s overall aim was to investigate the formal and informal ways that clinicians learn about patient safety – keeping patients safe from errors, mishaps and other adverse events – during their pre-registration training as students.
It sought to look at how patient safety and its associated problems were framed for four different professions (medicine, nursing, pharmacy and physiotherapy) across the academic, organisational and practice contexts. Its main objectives were to:

- identify explicit patient safety content for pre-registration students within the formal curricula
- explore the relationship between planned curricula and taught elements of patient safety
- describe the safety culture of day-to-day academic practice
- identify within organisational documentation any underlying ethos related to patient safety
- explore the organisational culture that students and newly qualified staff were exposed to
- examine and describe the practice cultures to which students and newly qualified staff were exposed.

About the Study:
For the study, the researchers initially looked at existing relevant research on the subject and then used a sample of 13 educational providers linked with five universities in England and Scotland that ran pre-registration courses for doctors, nurses, pharmacists, and physiotherapists. They then undertook case studies at eight of the providers (two for each health discipline) looking at different programmes, practice environments and models of teaching and learning there.

Practical findings:
Review of research
The researchers began by examining existing relevant research for each of the four healthcare disciplines they were focusing on – medicine, nursing, pharmacy and physiotherapy.

For medicine, the research already out there suggested that some medical schools felt that curricula which include generic skills such as team work, communication and reflection would improve patient safety.

In other schools, teaching related to specific aspects of patient safety was being introduced such as significant event analysis and crisis resource management.

In nursing, there was limited evidence to show how nurse educators were incorporating patient safety themes into their programmes and what impact such training had in practice.

Very little evidence existed on patient safety within pharmacy education and what there was, focused on awareness of adverse reactions and reporting procedures. Much of the research suggested there should be more emphasis on patient safety in the pharmacy curriculum with students having more exposure to clinical practice.

For physiotherapy, there was a lot of existing research on safe physiotherapy practice, but little about education for this. The evidence was focused on how students learn safe technical skills mostly from their supervisor on placement and by being able to have their own caseloads.

Studying the courses and the people
The researchers chose 13 educational courses based at five universities that ran traditional and innovative courses for doctors, nurses, pharmacists and physiotherapists.

They gathered examples of existing curriculum documents to analyse and interviewed course directors and similar informants.

Documents looked at were guided by five chosen areas – medicines; infection control; moving and handling of patients; risk management; and communication.

To look at NHS ethos, the researchers chose five overarching areas as relevant to patient safety – complaints procedures; whistle blowing policies; critical incidents and incident reporting policies/procedures; quality improvement and clinical governance; and staff induction materials.
For the eight case studies, the researchers carried out in-depth investigations of learning and practice by students and newly qualified practitioners in universities and practice settings in relation to patient safety. They gathered data to explore the:

- planning and implementation of patient safety curricula
- safety culture of the places where learning and working happened
- student-teacher interface
- influence of role models and organisational culture on practice.

This data came from observation, focus groups and interviews.

**Medicine**

Four medical schools were included in the study, chosen specifically because of their differences including a range of age, use of problem based learning, and different styles of placement based learning.

The researchers found that the current drive in the NHS to prioritise patient safety had been taken on board by medical course leads who were incorporating patient safety into both formal and informal curricula.

There was less mention of assessment than might be expected, in all stages of these courses, which the researchers said could show the ‘implicit’ rather than ‘explicit’ nature of patient safety in the curriculum, or showed that safety was part of overall competence and therefore all assessments were relevant.

Interviews revealed that people struggled to come up with a precise definition for patient safety. There was no support for patient safety to be made a stand-alone topic in courses, but people were keen that relevant content and outcomes should be more explicit.

Assessments of students could be improved upon, they also found, with more consideration given to patient safety shown by linking it to competencies and outcomes, as a way of demonstrating safe practice. Some courses’ content showed important gaps on areas such as how and why errors happen; inter-professional team based delivery of safe care; how to learn from errors; and the circumstances in which mistakes and underperformance happen.

Most people interviewed accepted the value of having good role models and the opportunity to question lapses in practice, but some had doubts how ‘safe’ it was to highlight and explore mistakes.

**Nursing**

The four nursing programmes being studied were at degree level and although the structure varied between them, all followed a broadly similar pattern.

The researchers found that patient safety was not visible as a specific module or theme but as a series of statements about safety.

Most lecturers struggled to define patient safety as a distinct concept and they as well as students felt patient safety was not a separate topic but underpinned all aspects of nursing programmes. Lecturers valued and promoted up to date, evidence-based safe practice and for students, patient safety was about learning to deal with real issues for real patients.

It was felt that it was the students’ responsibility to ‘be on the look out’ for errors and be aware of hazards.

Some students felt they were taught defensive practice – what not to do – and said placements were important in consolidating learning about patient safety.

The role of mentors was critical in this area, the researchers found, and relationships between the students and their mentors were vital to student learning, through their availability, willingness to teach and attitudes to questioning.
The mentor relationship affected how confident students felt to challenge unsafe practice in other staff. Safe practice could be influenced by resource issues, peer pressure and client factors, the study showed.

Students felt they should be made more aware of NHS Trusts’ approaches to risk assessment and suggested having ‘patient safety debriefs’ after placements and more support in some clinical areas from practice placement facilitators.

**Pharmacy**
The pharmacy schools examined for this study were chosen because of their differing histories and characteristics.

The researchers found that pharmacy students highly valued the practice context for learning about patient safety.

Pharmacy students said that ‘ad hoc’ voluntary work experience was an important factor that compensated for limited formal clinical exposure and under-addressed patient safety elements such as professionalism and systems and processes.

In academic settings, the researchers found that patient safety content was often described as embedded throughout the curricula.

By studying three courses, the researchers noted that the courses’ core content was often similar, but several patient safety topics were notably absent, including the how and why of adverse events and error, root cause analysis and quality assessment.

The courses also lacked reference to the organisational context of patient safety and there was only limited exposure to this during formal planned visits and tutorials.

Funding for formal clinical exposure for pharmacy students was a large issue affecting the schools, but the researchers’ findings demonstrated a marked difference in frequency and scope at the two case study sites.

The findings were highly relevant, said the researchers, given the fact that in April 2008, the government’s pharmacy White Paper had acknowledged limitations in undergraduate education in relation to the “opportunity for undergraduate pharmacy students to develop throughout their education a professional, patient-focused, clinical approach to practice.”

**Physiotherapy**
In both of the physiotherapy courses examined for this study, the curriculum material identified as directly addressing safe and effective professional practice was quite limited.

All of the people interviewed considered patient safety as pervading the whole practice of physiotherapy.

Most people felt that learning about patient safety was integrated throughout the courses and students said they learned about patient safety all of the way through their training.

The researchers found more evidence of learning in relation to patient safety in practical sessions and on placements.

The very fact that students and newly qualified staff learned how to conduct procedures competently, became aware of all of the possible adverse reactions of doing something and were able to assess possible risks, helped them to ensure patient safety.

It was clear that assessment was important in university in driving and consolidating learning about patient safety.

The students suggested that major factors in the quality of placements in relation to patient safety
were the attitude of educators and the numbers of staff.

They considered educators on placement as role models (both good and bad) with a strong influence on students’ learning.

Safety was inbuilt to physiotherapy work and training by clinical educators, who felt that developing observation, clinical reasoning and risk assessment were crucial to patient safety.

The researchers felt that students needed to be empowered to question and challenge unsafe practice, procedures and processes without fear of being punished.

**Views from the stakeholders**

Overall, people interviewed across all the sites said that patient safety had become a higher priority for NHS Trusts in recent years including their own.

Within the organisations examined, incident reporting was a key feature of the patient safety agenda.

Some staff, however, were confused about reporting or too busy to report, the researchers found, and generally, students were either not engaged or not even aware of incident reporting schemes. If they were aware, they might not have access to systems in the Trusts.

**Summary of main findings:**

- Different universities teach patient safety in different ways and some have it as specific teaching sessions
- No one interviewed in the study wanted patient safety to be formalised as a stand-alone topic in training courses for healthcare professionals, but people were keen for relevant content and outcomes to be made more explicit
- Healthcare professional students have little preparation on practical exercises such as incident reporting during their training
- Students, lecturers and course directors often struggle to define ‘patient safety’ precisely and believe it is an aspect of everything that health professionals do in their work
- Relationships between students and their mentors were crucial to student learning and their attitudes to questioning, affecting how confident students felt to challenge unsafe practice in other staff
- Pharmacy training courses’ content was often missing several patient safety topics such as the how and why of adverse events and error, root cause analysis and quality assessment
- Regulators, professional bodies and quality assurance agencies were considered to be influential in patient safety curricula.

**Conclusions, recommendations and implications for practice and policy:**

- Patient safety is more implicit than explicit in curriculum documents and for most students it is experienced as integrated throughout their studies
- Role models are crucial for demonstrating appropriate attitudes, behaviour and safe practice
- Training should be developed for clinical or placement educators in all healthcare disciplines who need to be effective role models showing students how to learn about patient safety
• Curricula should include developing students’ capacity to constructively challenge unsafe or non-standard practice

• All courses should be able to identify an integrated thread of teaching and learning related to patient safety in their curricula and assessment for this element should be identifiable

• Courses should create opportunities to involve students in meeting with patients and learning about their experiences and concerns, either on placements or by using ‘expert patients’ who offer specific teaching on safety issues

• Curricula should be revised to include issues such as handover challenges, epidemiology, risk assessment and, for pharmacy, the how and why of adverse events and error, root cause analysis and quality assessment.
Chapter 5 – Ethnographic Studies and Synthesis Work

5.1 Introduction by

Professor Mary Dixon-Woods
Professor of Medical Sociology, University of Leicester

The four ethnographic studies included in the Patient Safety Research Programme vividly illustrate the importance of direct observations and conversations with people working at the ‘sharp end’ of healthcare. The studies are conducted within different genres. McDonald et al’s ethnography of operating theatres is located with a sociological tradition, and includes a focus on organisational context, and on the roles and social identities of staff. The others (Wolyshynowych et al’s study of patient safety in an accident and emergency department; Healey et al’s study of patient safety in surgery; and Catchpole et al’s study of errors in operating theatres) lean more towards the psychological tradition, and make more use of highly structured methods of data collection and analysis. Taken together, the reports offer powerful insights into what goes wrong and why in the settings studied, as is clear from just three examples chosen from the many in these studies.

First, a striking feature across all the reports is the high number of distractions and interruptions to the work of staff both in surgery and A&E. Some of these are perhaps unavoidable. But many arise because distractions are routinely tolerated. The studies, for example, describe individuals not involved in surgery walking in and out of operating theatres (sometimes in violation of hygiene protocols), and phone calls (including personal calls) during operations. The hierarchical structure of surgical teams seemed to make these distractions difficult to control, with some evidence that senior staff were more prone to committing violations than others: an important finding of the study was there was often confusion about authority chains, including who was in charge and on what authority. Distractions also arose because of the immense pressures on the operating theatre schedule, and difficulties in the availability of the proper equipment and resources. Distractions and interruptions need to be recognised and dealt with as a problem by teams and organisations.

A second important finding offers some explanation for why incident reporting is sub-optimal. Some (perhaps even most) incidents simply never get reported at all. There are many reasons for this, but the studies show that whether staff identify the incident as a learning opportunity is critical. One surgeon said that his being distracted by the curvature of the scrub nurse’s legs was not something anyone else could learn from, while seven ‘major failings’ that occurred during 24 operations were never discussed in any forum after the operations had ended. Much more attention is needed to how people at the sharp end define things as problems and learning opportunities. Convincing people that incidents should be reported is likely to be most effectively addressed by firm evidence showing the benefits, but this is difficult to produce when, as the studies show, most incidents are followed by a successful rescue. These successful rescues can themselves be a safety problem, because, as Diane Vaughan’s analysis of the Challenger disaster demonstrates, people learn the wrong lessons.

Third, the need for patient safety solutions to be well fitted to the problems they are trying to solve, and that recognise the ‘heritage’ effects of existing cultures, organisations, and environments, is evident. Some problems identified by the studies – such as surgeons not communicating about starting the procedure or the patients’ notes being unavailable – are amenable to being addressed by checklist type processes. But proceduralisation may be a poor solution to other problems, and may cause unproductive resistance by staff. Moreover, routinisation of procedures can generate its own pathologies, including people enacting them ritually even when they are inappropriate. The risks of having too many procedures/checklists are not trivial, and there are also risks that the real sources of some problems (such as shortages of resources, staff, equipment, organisational design, or poor behaviour) do not get addressed.

A final point worth of note is the difficulties that some of the research teams had in accessing the fields they wish to study. The ethical issues that arise when conducting ethnographies where the staff are reluctant to be observed, and refuse to allow ‘their’ patients to be approached about patient safety studies, need to be more thoroughly debated. Well-informed guidance for Research Ethics Committees should be made available. But there is also a wider issue here about staff perceiving that they are part of a closed social world that should be immune from external scrutiny. A possible way of penetrating such worlds may involve building on the kinds of collegial logic they express, and co-opting insiders who are specially trained to work with colleagues.
5.1.1 Operating theatres – the threats to patient safety
Professor Stephen Harrison

Key Messages:
- Opinion on what safe practice is can vary significantly between different NHS staff
- Different groups of staff have different beliefs about adverse events, risk and error reporting
- Doctors in particular often do not consider reporting of errors as a worthwhile exercise
- The impact that fear of blame has on reducing error reporting may have been overestimated, meaning the government’s drive to remove fear of blame will not be as successful as hoped
- Doctors need to be convinced that reporting will improve patient safety as many believe errors are an occupational hazard and are inevitable
- Attitudes to adverse events are deep rooted, with doctors holding very different views from managers and using the same words (risk, error etc) to mean different things
- Managers have particular views of safety problems as just being solved with better systems/management, but blindly following protocols can increase risk too
- Enforcing new standardised systems for reporting adverse events nationally may worsen tension between different groups of staff working in operating theatres because of the very different opinions they hold on the issue.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2 billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400 million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

A significant proportion of adverse clinical events (almost half) are linked to surgery – seen to be a high risk area – and a third of referrals from NHS hospitals and community trusts to the national body that monitors doctors’ performance are to do with surgeons.
Aims of the Study:
The study aimed to explore the individual and group values, attitudes, perceptions, competencies and patterns of behaviour of those staff working in a hospital operating theatres department. It also set out to investigate a Patient Safety Training course for hospital staff that was intended to foster a more safety conscious culture.

About the Study:
A member of the research team was based within the operating theatres department of a large teaching hospital in the north of England on a full-time basis for 18 months.

This person observed activity within the department and had informal conversations as well as formal interviews with the staff there. The data collected were added to an analysis of documentary evidence such as hospital policies, notes of meetings and organisational charts. At the start of the research, the existing system of risk management at the trust was being overhauled. Developments included the:

- creation of a new communication and accountability infrastructure for incident reporting and risk management
- redesign of the incident reporting system and form
- introduction of trust-wide induction and training programmes for incident reporting, root cause analysis and risk management in general.

The study method was ethnography, meaning trying to understand behaviour and culture by going out and talking to people wherever they are and observing what they are doing, whatever it is they do. This kind of research is usually deeper and more intimate than other types of research, getting close to research participants, spending time with people in the natural context of their daily lives.

Practical findings:
Interviews with the staff at the operating theatres department showed that participants did not appear to have been inhibited by the presence of the research observer nor did they appear to change their behaviour. As well as observation and informal exchanges and conversation, 80 formal interviews were carried out with staff members.

The observer also kept a personal research diary to record their reflections of the process as well as a detailed descriptive record of their observations, conversations, and interpretations.

During the 18 months, the observer saw adverse events and near misses, but the researchers wanted to maintain the goodwill of hospital staff and minimise their reactivity, so it was decided that the work would not focus on specific adverse events identified by researchers as a subject for interviews and conversations.

Work processes
The researchers found that hospital managers perceived events and processes – such as risk, theatre timetabling, and theatre processes – as something to be managed proactively, in a systematic fashion. Managers saw their task as managing and solutions to perceived problems were seen in terms of improving control by management. Although some managers like to treat each part of the hospital’s system as a discrete entity, this is not always helpful, says the paper.

The work of the hospital operating department can be seen as part of a complex system where work in operating theatres is heavily dependent upon other hospital departments, it says.

The researchers carried out a mapping exercise of the processes at the trust and what flows there were between departments. They also looked at policies and protocols alongside observational and interview material.

It emerged that relationships between the operating theatre and other departments were subject to “breakdowns” that disrupted the flow of work in theatres.
The daily activities and procedures of the theatres are dependent on the performance and integration of other hospital processes, says the paper, especially communication between departments and the transfer and exchange of resources, services, information and skills.

Just one delay in one or two exchanges of goods or services from another department could bring the provision of surgical care in an operating theatre to a standstill or put considerable pressure on the staff there, the report says.

Delays were caused by lateness of transfer of patients from surgical wards; problems over provision of high dependency unit beds; weak relationships with the histopathology and radiographic services (late test results and X-rays); and poor relationship with Sterile Services.

With the latter, the researchers found that six of 25 scheduled procedures were delayed because the surgical instruments supplied were either late or the wrong types of instrument.

However, the researchers said these inter-department delays were small and did not have a large impact on the overall workings of the operating theatre. The theatres had come to expect, tolerate and work around these delays. Some of the longer and multiple delays had more of an impact and resulted in staff working faster to make up time or, in some cases, the scheduled theatre list and order of patients would be changed.

These constraints, changes and uncertainties could have an impact on safety at work, says the paper, and lead to people becoming irritable and erratic, strained relations between staff, and normal routines and checks would sometimes be missed or cut short.

**Safety culture**

The researchers found that the definition of error varied depending what group of staff was asked, as did the definitions of what counts as risky and safe behaviour.

When it came to views of safety, protocols, error and risk, nurses saw being professional as developing, supporting and following protocols, whereas doctors felt the opposite, as protocols would threaten their medical identity and be too restrictive in some cases because every patient is different.

Nurses placed less emphasis on good outcomes and more on following protocols, checklists and written policies and processes, believing that standardised approaches were the best way to ensure patient safety.

Doctors in particular did not see error reporting as worthwhile, the researchers found, because they had the view that many mistakes were inevitable and not preventable, so there was limited potential for learning from mistakes.

The nature of the work of doctors in operating theatres was described as “dynamic and uncertain”, according to the paper, hence doctors had to be able to react quickly to changes and tailor treatments for individual patients. This explained their resistance to standardised protocols or guidelines that had to be followed.

These different opinions cause tension amongst staff, says the paper, adding that some nurses consider doctors’ non-compliance with protocols as unprofessional and sometimes a risk to patient safety.

**Errors and adverse events**

Different groups of staff viewed the factors that predisposed error in different ways, which may explain why staff appeared to have firm opinions about the nature of the problem, despite anything that might happen to contradict these opinions. Managers and nurses both saw adverse events as largely preventable and supported guidelines, rules and planning processes.
Doctors, however, did not share the same faith in systems to maintain order and manage risk. They seemed to view lapses in practice as inevitable and this could mean they did not consider potential adverse events as risks at all, said the researchers, but as inevitable occupational hazards.

Medical staff complained about conditions that increased risk in the operating theatre (such as lack of suitable equipment) but seemed to see it as part of their job to cope under such circumstances.

**Patient Safety Training course**
A Patient Safety Training (PST) course was developed at the trust, led by two consultant doctors outside of the trust management structure to create a risk conscious culture there.

It was designed and developed by enthusiasts, focused more on why patient safety was important and what staff think of safety issues rather than the practical aspects of risk management in the trust.

During the period of this research, a full day PST course was run every month with between 12 and 25 people attending and it proved popular with high demand for places.

The researchers said the course was based on training conducted in the aviation sector and adapted for health care, and despite its good intentions, it contained significant conceptual weaknesses.

The presentation of the course was highly developed using various visual-audio aids, but the detail and volume of information was too great to be effectively delivered within a single day event.

The course’s objectives were to foster a risk conscious culture through providing staff with a new way of thinking about patient safety based on the principles of human factors and by giving staff a toolbox to improve the safety of their work.

The researchers, however, said they were unable to assess the impact of the course on working practices and the development of a risk conscious culture.

**Summary of main findings:**
- Opinions vary greatly between different groups of NHS staff as to what exactly is safe practice
- Doctors’ views of just how useful preventive measures are on adverse events are very different to those held by managers and nurses
- Work done in operating theatres is heavily dependent on other hospital departments schedules and smooth running so workload planning and theatre timetabling should take into account wider system factors
- Doctors do not always see error reporting as worthwhile partly because they believe there is limited potential for learning from other people’s mistakes and say some mistakes are inevitable
- The government’s policy of seeking a safety culture in the NHS instead of a blame culture may be missing the point – it does not take into account the views, beliefs and values of different staff groups
- Doctors seem to have a deeply-held view that errors are just part of the job that cannot be prevented and this view is ingrained into the profession when they are being educated
- Attempts to impose written rules on patient safety and to define non-compliance by staff as either an error or a violation are likely to be fiercely resisted.
Conclusions, recommendations and implications for practice and policy:

- Further research involving a clinical observer, and ideally someone who participates rather than being a “fly-on-the-wall” observer, could allow extra insight into practices and safety in clinical settings.

- Trusts should think more of the whole picture and system-wide factors when deciding on workload planning and theatre timetabling – operations are affected by a lot more than what is happening just in the theatres.

- Work needs to be done looking at medical education where doctors are taught to believe that errors are occupational hazards that cannot be prevented – otherwise attempts to increase error reporting will fail.

- Research into the “unwritten rules” that govern behaviour in NHS organisations – how they are produced, maintained and accepted – would be worth doing in the future because currently there seems to be a denial that they exist and simply coming up with new “high-reliability” processes will not work.

- Written protocols on patient safety are all very well, but the unwritten rules of theatre etiquette mean that it is unlikely that nurses will challenge doctors in operating theatres and doctors will not see nurses as professionals whose views are equally valid within the theatre.

- Future studies that look at the factors that can lead to errors in health care could be more useful than carrying out investigations that begin from assumptions made about safety culture.

- Other studies could look at several sites and different types of site to allow for comparisons to be made between different types of staff such as GPs.

- Research on the impact of system pressures (such as financial pressures and waiting lists) on behaviour in operating theatres could be worthwhile.
5.1.2 How to improve patient safety in surgery
Professor Charles Vincent

Key Messages:
• Error reporting systems have limits – relying on self reporting and subjective interpretations of events – so more objective, impartial and real life experience assessments are needed, such as precise models of performance

• Models of performance in surgery are needed to account for the technical aspects of an individual’s work and teamwork in the operating theatre – they help measure performance and help to remove ineffective practices

• While developments in technology and procedure in surgery have speeded up to change the work done in operating theatres, research into human resource and human factors aimed at improving working conditions, safety and performance are lagging behind

• Surgeons, nurses and anaesthetists believe teamwork in operating theatres is satisfactory but say communication is inconsistent and not fully effective

• The importance of teamwork is undervalued, while individual leadership and resilience tends to be over-relied upon

• Interruptions and distractions during operations can impact on team performance and surgical outcomes, becoming a potential threat to patient safety

• Multidisciplinary team training for all staff working in surgery using simulated scenarios could help improve team performance, identify their skills and/or lack of skills, and potentially improve patient safety

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs. Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
• explore the size and nature of the problem
• understand the factors causing harm
• develop interventions to reduce errors
• assess how effective have the attempts to reduce errors been
• implement ways of guaranteeing change in people and organisations.

A significant percentage of adverse events (around half) are associated with surgical procedures, but it is estimated that at least 30-35% of major complications in general surgery in the UK could be avoided.
Aims of the Study:
The centre of research carrying out this work has a general aim of improving safety in healthcare. The broad aims of this research programme were to
- identify various aspects of the surgical system that compromise safety
- develop a theoretical framework to improve safety and reliability in surgery
- develop measures of performance for assessment and training.

About the Study:
The researchers used several approaches for this work. They:
- carried out an observational assessment of individuals’ surgical skills
- interviewed staff to measure team performance
- did an observational assessment of team performance in the operating theatre
- carried out a separate observational study into interruptions and distractions
- developed interdisciplinary team training in surgery using simulated training scenarios in one hospital.

Practical findings:
Healthcare organisations rightly place a great deal of emphasis on the development of the professional skills of individuals. However, they do not always consider the big picture and the wider systems and processes which affect the way people work.

Factors such as study of workplace design, human-machine interface design, teamwork, culture and ability to acquire knowledge, are all important to achieve high performance in surgery, but are sometimes neglected in the NHS.

The researchers carried out a series of overlapping projects all aimed at developing their knowledge of the process of surgical care.

Skills assessment
A key factor in determining surgical outcomes is the technical skill of a surgeon and their performance in the operating theatre.

The researchers designed their own skills assessment instrument, related to models of surgical performance derived from an analysis of laparoscopic cholecystectomy – a very common surgical procedure used in minimally invasive surgery.

They recorded a series of such operations (laparoscopic cholecystectomies) carried out by consultants and trainees and then used the assessment instrument. They found that trainees made minor errors in 23% of operations and major errors in 7.7% of operations. These mistakes were all corrected at the time because they were supervised by a consultant.

Consultants made minor errors in 46% of operations and major errors in 6.6% of operations and these were all corrected. It was possible, said the researchers that trainees made less minor errors because they were being guided by a consultant so were prevented from making mistakes.

Team performance
When measuring team performance, the researchers used a model that said effective functioning of a team depends on several factors:
- team structure and skills
- the environment in which they are working
- the processes and guidelines underpinning teamwork
- members sharing an understanding of the roles and responsibilities of all members and how they work together.

The researchers, therefore, designed an interview questionnaire to get information from staff in
operating theatres about their perception of team performance in surgery. They interviewed six people from each one of the four disciplinary groups involved in surgery – surgeons, anaesthetists, operating department practitioners (ODPs) and nurses.

Results showed that 75% of all the people interviewed said the team structure they most often work in, was not ideal. Of all the groups, nurses felt most strongly (67% of them) that the operating theatre professionals worked as a single team, but this view was not shared by any of the surgeons or anaesthetists and just 33% of the ODPs agreed with the nurses.

Groups tended to understand their colleagues' roles better than colleagues understood their own role, but most agreed that surgeons did not understand others' roles as much as they thought they did. Overall, the people interviewed said teamwork was satisfactory in the operating theatre, but with room for improvement.

Three quarters of the interviewees indicated they would like a change to the current team structure, but there was a lack of agreement as to the ideal structure to replace it. They all agreed good communication was important in effective teamwork, but said communication problems often happened.

**Observing team performance**

Using a process of observation to assess teamwork in the operating theatre, the researchers looked at the surgical process under the categories of patient, environment, equipment, provision, and communication tasks.

They also rated staff's behaviour on cooperation, leadership, coordination, awareness and communication. All this information was analysed alongside surgical outcome data. Data was collected from 50 general surgery operations in a single operating theatre. The operations were varied as were the ages of the patients involved. The researchers found that overall team performance in the operating theatre was reasonably high but variable. However, the completion of operative tasks was below best practice guidelines and below the standard of performance expected of high reliability teams.

Communication between the team varied in quality and quantity and patient notes were missing in about one eighth of the cases. There were frequent failures to check both surgical and anaesthetic equipment and failure to confirm procedures verbally.

Although the outcomes of all the operations observed were good (there were few serious complications), some lapses in tasks being completed were potentially a threat to patient safety, said the researchers. In more than 70% of cases, there were delays or changes to the case-lists due to several reasons including the patient journey to theatre, busy ward staff or porters, bed allocation processes, the surgeon or anaesthetists’ absence, incomplete notes, and lack of equipment.

The researchers rated communication lower than other behaviours and this can have serious implications. For example, they said verbal communication to confirm antibiotics were being given to patients was only done in 53% of cases, which may have influenced infection outcome.

**Interruptions and distractions in the operating theatre**

The researchers also carried out a separate observational study, in which they tried to define and measure influences on surgical team performance that collectively could become worrying distractions or interruptions to their work.

They looked at 50 general operations from a single operating theatre in a NHS hospital and took into consideration many factors including phones, bleepers, radio, conversation irrelevant to the case, communication difficulties, external staff, lack or failings of equipment, and workspace.

The results showed a high frequency of distraction and interruption and the most common events were bleepers going off in theatre – 21 times during one operation - movement behind the video monitors that guided the surgery, and conversations that were irrelevant to the procedure.
Equipment not working properly was another source of interference in theatre and the researchers said that in some cases, the operating theatre space appeared to function like a thoroughfare because of the amount of people coming and going during operations.

These interruptions and distractions could impact on team performance and surgical outcomes, said the researchers.

**Team training**
There is a lack of interdisciplinary team training in surgery to improve performance reliability and safety, according to the researchers. To address this, they developed simulated scenarios in a NHS hospital and came up with team training in crisis management for the whole surgery team.

The idea was to assess and train surgical teams with the belief that such training can enhance shared understanding among members of the team about effective teamwork and improve their skills at dealing with crisis situations.

By using a virtual operating theatre, fully equipped and functioning, they piloted realistic surgical scenarios.

In all, 16 simulations of a single scenario were carried out and each session involved a surgeon, anaesthetist, scrub nurse, and an ODP taking part.

All participants found the simulations beneficial and gave positive responses, leading the researchers to conclude that such training is feasible on a national scale and gives useful data on technical and non-technical skills that could improve team performance and patient safety.

**Summary of main findings:**
- From a sample, consultants made minor errors in 46% of operations and major errors in 6.6% of operations, while trainees made minor errors in 23% of operations and major errors in 7.7%
- Communication between the operating theatre team during procedures is variable in terms of quality and quantity
- There is a lack of formal exchanges between the different groups of staff during operations about essential information and completion of basic procedural tasks
- Almost three quarters (70%) of operations are delayed or case lists are changed
- Numerous distractions and interruptions occur during surgery such as bleepers and phones going off, faulty equipment, and external staff entering and leaving the theatre
- Team training of all staff involved in operating theatres using simulation scenarios proved popular with staff who said it had real benefits and could work nationally
- Teams in the operating theatre are lacking formalised interdisciplinary teamwork, have unclear team structure and role allocation, and coordination and communication are often ineffective.

**Conclusions, recommendations and implications for practice and policy:**
- Future studies could examine the causes of surgical errors and ways to prevent them, now that this research has shown that surgical errors can be classified and reliably assessed
- Worthwhile research could be done on the operating theatre environment to look at the drawbacks of distractions and interruptions
• Research into the feasibility of multidisciplinary team training for the whole surgical team in using simulated scenarios on a national scale could be worthwhile

• Potential research into the area of decision making in surgery is worth considering as this is a crucial area – it is high risk and often irreversible – with many dimensions to investigate, such as how technology can support decisions and how to assess the process of decision making

• Considerably large research is needed into the many questions that remain over teamwork in surgery, looking at ideal team composition; are some roles overburdened with work; what information is needed by the team before, during and after operations; and does the education system for each of the health professions give enough focus to teamwork in practice

• A large scale examination of the performance of surgical teams would be a powerful way of improving safety culture in the NHS and overall improvements in the wider healthcare system

• The researchers planned (at the time of publishing) to carry out research into the ways that surgical patients can help to enhance their own safety.
5.1.3 How to improve patient safety in A&E
Professor Charles Vincent

Key Messages:
• Delays are the most commonly reported incidents in A&E where time is a crucial factor to judge performance of departments

• Analysing barriers – a method of error reduction in other industries – is a useful approach and can be adapted and used in healthcare settings

• Patient safety could be affected by the fact that nurses in A&E have to deal with high levels of communication as part of their daily work

• There is a real need to reduce the sheer volume of communication load that nurses in charge of A&E departments deal with on a daily basis

• The efficiency of triage for patients is not always better with more senior staff and is more affected by external factors such as the need to carry out non-clinical tasks

• Electronic reporting systems are expected to improve the rate of clinical incident reporting and give a clearer picture of the types of incidents that occur in A&E, allowing more effective interventions to reduce incidents and improve patient safety.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

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As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
• explore the size and nature of the problem
• understand the factors causing harm
• develop interventions to reduce errors
• assess how effective have the attempts to reduce errors been
• implement ways of guaranteeing change in people and organisations.

A&E is an area with high risk and potential failures built in to the nature of the work, so is a desirable environment for research into understanding and improving human performance under demanding conditions.

Aims of the Study:
The study was designed to explore certain issues and solutions in an emergency department regarding patient safety that could be transferable to other departments.

The work was meant to be a prelude to more focused studies on issues such as decision making and communication in the future.
About the Study:
The work for this research was all carried out within a single emergency department in a London teaching hospital over a two year period. The researchers used several approaches for this work. They:
- carried out a study to evaluate the incident reporting system
- conducted a case analysis on patient who experienced delays
- analysed barriers and safeguards and how these can help generate solutions to problems
- carried out a communications study
- studied triage to evaluate its efficiency.

Practical findings:
An A&E department is a complex and difficult environment in which to provide care, said the researchers.

Important topics to look at in the context of an A&E department included development and maintenance of individual skills; role of formal and informal communication; impact of working conditions on team performance; and the need to understand the A&E environment.

That environment was characterised by several factors including the multiplicity of work done there, uncertainty of what is coming, time constraints, and lack of feedback due to the nature of the patient’s journey in the hospital.

A&E is a crucial area to consider, said the researchers, because previous work had found that although A&E accounted for only a few percent of the total adverse events in hospitalised patients, around three quarters of those events were seen to be preventable – a higher proportion than in any other area of care.

The researchers carried out their work while the four-hour waiting time target in A&E departments in England was being introduced, so significant changes were happening which impacted on some of the studies.

The researchers carried out a series of overlapping studies all aimed at looking at the safety aspects of healthcare processes.

Incident reporting in A&E
Local incident reporting systems in hospitals are designed for staff to report errors or clinical incidents so lessons can be learned and they can help reduce the likelihood of similar incidents happening again as well as monitoring patient safety issues.

The researchers studied the incident reporting system at the A&E department to evaluate its use and effectiveness there.

They reviewed 13 consecutive months of data from the A&E section of the trust’s electronic database of clinical incidents, which included 174 incidents reported.

The biggest group of reported incidents were related to delays due to various factors such as a lack of porters or difficulty in arranging for patients to be seen quickly by specially doctors.

Other types of incident included drug related incidents and lack of facilities or equipment.

The severity of incidents varied and the most common type was ‘near misses’, which accounted for 95 of the 174 incidents, followed by ‘minor’, ‘moderate’ and just 20 ‘serious’ incidents.

The system had, however, led to positive action being taken by the trust as a result of the incident reports, such as new protocols and a quarterly newsletter highlighting lessons to be learned.
The researchers found internal weaknesses with the local internal processes in reporting incidents and said there were limitations with the information recorded on the database – it was incomplete, and some people classified similar incidents in different ways.

**Specific case analysis**
The researchers analysed a particular case of a patient who had chest pain but who had been missed at registration and therefore not identified by a nurse’s triage.

The incident happened at a busy time when staff were changing shifts and the patient received delayed treatment.

The researchers said this method could be a useful additional way of analysing incidents.

**Barriers and safeguards**
Barrier analysis is a method used often in the nuclear and chemical process industries to reduce error, but similar techniques that assess human reliability or error analysis are rare in healthcare settings.

The researchers set out to use this method of analysis in healthcare, looking at four main types of barriers – physical, natural, human action, and administrative – and what safeguards were in place to protect vulnerable objects such as patients from harmful objects or actions.

Using the example of medication error – a common medical error – the researchers asked two A&E consultants, one registrar, a matron, three emergency nurse practitioners, and a senior staff nurse about a medication administration problem and asked them to identify the barriers already in place to prevent the risk.

The staff identified 13 barriers or safeguards to the problem of ‘a medication prescription not checked by a nurse before being administered by the nurse’, most of which were administrative or related to human actions.

They also suggested 16 possible improvements covering many areas such as education and training, supervision and checking, feedback, resources, and cultural and organisational change.

Using this technique is feasible in healthcare, the researchers concluded, and the participants were enthusiastic about its potential as well as seeing that some of the improvements were actually implemented locally.

**Communication**
Poor communication between NHS staff can play a large part in medical error and interruptions are a part of the job, which disrupt memory and cause errors.

The nurse in charge of an A&E department is the lynchpin for communication there, said the researchers, so they decided to study levels and patterns of communication in this particular staff group.

For this study, 11 nurses in charge of the A&E department were observed while working and data were collected over a six-month period in 18 study periods. A small tape recorder was used to record the nurses’ speech and a researcher followed the nurses around taking notes. The researchers found there were 2,019 communication events overall, of which 59% were initiated by the nurses. The nurses were interrupted on 41% of occasions, i.e. where others initiated communication.

Around two thirds (65%) of nurses questioned said there had been no unnecessary communication events, but when asked what was the most annoying thing about the time period being studied in terms of communication, a common problem was trying to deal with too many things at once.

Overall, the study showed that nurses in charge of A&E had high levels of information exchange to deal with as part of their work.
The amount of interruptions that nurses have to deal with could pose significant implications on effective exchange of information and there was a danger of it having a negative impact on the quality of care.

**Quality of triage**
Triage, the process by which a patient is assessed for treatment or the most appropriate type of care, has been an increasingly pressurised event with the government setting time targets for people to be seen. The researchers wanted to evaluate the efficiency of the triage process from a systems perspective.

They observed 258 patients being triaged in the waiting room triage area over a period of two months. For the study, 16 hours of observations in triage were carried out as well as interviews with nurses, emergency nurse practitioners and a consultant physician. Results showed that patients waited, on average, just over 13 minutes from being registered on the computer in reception to entering the triage booth while the triage process took an average of just over four minutes to do.

The researchers found that it made no difference to efficiency or time taken if patients were seen by a more senior member of staff. Staff working in triage had to overcome many problems including language difficulties, patients presenting with an inappropriate medical history, and interruptions from other staff, visitors or other patients.

**Summary of main findings:**
- The A&E department recorded more near misses and minor events than serious or ‘moderate’ cases in its incident reporting system
- Most incidents reported in A&E are to do with delays because A&E is dependent on other departments, specialists and staff who are based elsewhere
- Nurses in A&E have to deal with high levels of communication as part of their daily work
- The process of barrier analysis (method of error reduction) is time-consuming but the results are highly beneficial and have a positive impact on patient safety
- Improving communication between healthcare staff by cutting the number of interruptions and minimising the amount of irrelevant or unnecessary information exchange could improve patient safety
- Patients waited 13 minutes and 33 seconds, on average, to be seen for triage and the triage process took an average of 4 minutes and 19 seconds to do
- Nurses in charge of A&E departments have to deal with significant numbers of interruptions during their work – 41% of all communication events.

**Conclusions, recommendations and implications for practice and policy:**
- There should be a review of the recently introduced (at that time) electronic reporting system
- Researchers could assess the effect of analysis tools on staff’s understanding of safety
- Work could be done to develop additional systems to redirect unnecessary communications for the nurse in charge of an A&E department
- A study looking at monitoring the effect of electronic handover at triage using non-clinical staff in different ways is also worth considering
- Other areas of potential interest include attitudes to the incident reporting process, staff
perception of board rounds and unscheduled returns to the A&E department

- Future research could investigate potential methods in which communication can be reduced for nurses in charge of A&E departments as well as strategies to cut the number of times that the nurse is ‘disturbed’ or ‘interrupted’ from what they are doing.
5.1.4 Errors in the operating theatre – how to spot and stop them
Professor Marc De Leval

Key Messages:
- Adverse events in surgery are more likely to be due to a coincidental buildup of several minor failures rather than due to an individual’s incompetence or negligence
- Improved training in teamwork and communication might help reduce the incidence and impact of errors in surgery
- A key barrier to patient safety is the fact that staff feel information from adverse incident reports will be used badly or not used at all, so feel it is pointless reporting incidents. There is an uneasy relationship between healthcare management and healthcare staff over patient safety issues
- Healthcare professionals need more evidence of the prevalence and nature of error in surgery and the benefits of sticking to safety practices
- Briefing surgical teams and de-briefing them can help avoid, capture and mitigate present and future failures
- Using computer models can be valuable in helping examine errors in healthcare organisations
- Fundamental changes are needed in healthcare in the UK to achieve high levels of safety in surgery.

Background:
There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a priority for the government. A drive to tackle these issues began shortly after the publication of a report by the Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS.

It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year. As well as setting up the National Patient Safety Agency (NPSA) in 2001, the government launched a large scale research programme to:
- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective have the attempts to reduce errors been
- implement ways of guaranteeing change in people and organisations.

A significant proportion of adverse clinical events are linked to surgery which is seen to be a high risk area.

Surgery is the setting where all parts of healthcare – diagnostics, treatments, technologies, skills, teamwork, infrastructure, management – all have some influence on the events than happen while a patient is in the operating theatre. Looking at the human factors in this setting is crucial in identifying
and reducing error with the intention of improving patient safety.

**Aims of the Study:**
The aims of the project were to:
- identify in advance latent or underlying conditions that may influence operating theatre team performance
- develop an integrated video and trained observer method for identifying active errors in the operating theatre
- apply operational research techniques to examine links between latent conditions and safety
- develop error management strategies to reduce the frequency of latent conditions and active errors.

**About the Study:**
The researchers carried out their work at two UK hospitals, looking at paediatric cardiac surgery initially and then orthopaedic surgery settings. Paediatric cardiac surgery was chosen because, although there is a low volume of such operations, it is considered to be extremely complex and a high risk area of surgery, whereas orthopaedic surgery is very high volume and reasonably non-complex. They identified and assessed errors in surgery using direct observation, video recordings to evaluate non-technical skills; assessed safety culture and how resilient health care organisations were; and used computer simulations to examine aspects of hospitals and how they operate that might increase the chances of surgical error.

**Practical findings:**

**Identifying and reducing errors in the operating theatre**
The researchers said that examining the causes of errors in the healthcare system rather than blaming individuals was essential to avoid adverse events in the future. To assess errors in surgery, the researchers used three methods, direct observation by expert observers, using video recordings to play back events, and evaluating the non-technical skills – teamwork and communication – apparent during each operation.

They found that small and apparently unimportant errors in surgery can accumulate to create bigger problems and patient safety incidents, which indicated a need to reduce these small problems. Much could be learned from other industries, they said, such as the use of non-technical skills in how to reduce these small problems and avoid or deal with errors better when they happened.

**Paediatric cardiac surgery**
In paediatric cardiac surgery, 24 cases were studied over a 10-month period. The researchers wanted to develop a method for measuring systems deficiencies in surgery, examine the types of failure in cardiac surgery and how often they happened, and investigate the change from a minor to a major failure. They found that in the 24 operations studied, there were 366 minor failures and seven major failures though all patients in the study survived.

The minor failures (of which there were 29 different types), were most commonly to do with communication and coordination, absences from theatre, and equipment failure. Longer and more risky operations were likely to have a large number of minor failures as increasing demand on the surgery team increased the chance of human error, said the researchers. The common minor errors happened often and were tolerated and not reported.

Using video recordings of operations was useful for examining the causes and origins of failures, said the researchers, which may have begun a long time before the failure became obvious. However, there were ethical difficulties in using the recordings.

**Orthopaedic surgery**
In orthopaedic surgery, 20 cases were studied, mostly involving total knee replacement surgery and total hip replacement surgery. All the operations were successful, but the researchers noted 421 minor failures and one major failure, which was resolved. The major failure came about indirectly as a result of several other issues such as uncertainty, high workload, task requirements, non-technical errors and the introduction of new technology into the operating theatre.
There were 20 different types of minor error and the most common were distractions, equipment management failures, safety consciousness failures and coordination and communication failures. Most often noted threats to safety were cultural and organisational problems and, as with paediatric cardiac surgery, non-technical errors happened more often than technical errors. People on the surgical team had considerable skills and competence, the researchers said, because decision making and diagnostic errors were the least frequent type of failure noted.

**Major failures**

Eight major failures were identified across both types of surgery, which represented clear risks to the patient. All were associated with a sequence of minor failures. They either accumulated or happened at a critical phase in the operation. This effect was amplified in high risk cases because they are longer and more difficult, often feature more minor failures, and because they generally have more critical phases.

The most serious failure – a potentially dangerous bleed – was triggered by a single event that is known to be a potential complication with that particular operation, but was exacerbated by a further sequence of small problems.

Other problems included one where a surgeon forgot a key surgical step, and another where blood was being filtered from the patient but was accidentally not returned. Despite these failures, all the patients recovered from surgery. Two of these failures were briefly described in the post-operative surgical report, the researchers found, but no other record of these events was kept, so nothing was learned by the operating teams about how these situations might be avoided in the future.

**Non-technical skills and errors in surgery**

The researchers looked at non-technical skills in healthcare, meaning the cognitive or mental skills (decision-making, planning, situation awareness) and social or inter-personal abilities (team working, communication, leadership), that people possess and a team show during simulated or real events. It is likely, they said, that the ability of a surgical team to work well together has a huge impact on operative performance.

The researchers gathered non-technical data from observing minor errors, and from independent video observation using a scale derived from the aviation industry.

Non-technical errors were much more common than technical ones, and they concluded that because non-technical performance of people in the surgical team can influence the success of surgery (particularly cardiac surgery), it should be assessed alongside technical performance.

They also found that teamwork between surgeon, anaesthetist and perfusionist (the health professional who operates the heart-lung machine during cardiac surgery) was critical in cardiac surgery, whereas the key relationship in orthopaedics was between the surgeon and the scrub nurse.

**Assessment of safety culture and resilience of institutions**

The researchers piloted three tools to assess safety culture and resilience of healthcare organisations. The first tool was called the Checklist for Assessing Institutional Resilience (CAIR) which studied the structure and procedures in place for monitoring, avoiding and managing errors at organisation level.

The second was the Incident Reporting and Attitude Survey (IRAS), which collected data from healthcare practitioners on the management of and attitudes to the collection and distribution of safety information and critical incidents.

The third was the Operating Theatre Team Management Attitudes Questionnaire (OTTMAQ), which examined the staff’s perception of team and individual performance in relation to safety in surgery. Collecting data for the CAIR was intensive, said the researchers, and it took staff up to 25 minutes to complete each of the IRAS and OTTMAQ questionnaires. Despite considerable efforts to encourage
staff to participate, there was a low response rate, which limited the conclusions that could be drawn from the data.

Nevertheless, the researchers said this showed organisation weaknesses in areas such as dissemination of findings of incident reports and investigations to clinical staff, and involvement of clinical staff in patient safety discussion at management level. IRAS and OTTMAQ data were similar, and showed that attitudes to safety were better in comparison to other similar studies.

Overall, healthcare staff felt that information regarding incident reports would either be badly used or not used at all. This discouraged them from error reporting. However, in general, the participants said staff should raise concerns they have over the actions of others regardless of hierarchy or professional boundaries and many said team members should openly discuss their differences with each other.

Mathematic modeling
Another part of the work done by the researchers was to use computer simulations of healthcare organisations to see how they affected patient safety. Computer simulation is one way of predicting system behaviour using a mathematical model of interaction between different parts of a complex system. They looked at various simulations involving patient admission and discharge, bed management on the ward, diagnostic procedures, and cross-matching of blood.

The researchers found that using this simulation method was feasible and helped to identify latent safety issues in a hospital’s system as well as helping to evaluate alternative strategies for reducing threats to patient safety.

Summary of main findings:
- During 24 operations carried out in paediatric cardiac surgery, there were seven major failures and 366 minor failures noted by an expert observer, but no serious injuries
- During 20 operations carried out in orthopaedic surgery, there were 421 minor failures and one major failure, which was resolved, but no serious injuries
- Some minor errors that happen frequently during surgery are usually tolerated and not reported afterwards. None of the events reported in the study appeared in any incident report or were learned from
- The non-technical performance of people in the surgical team can influence the success of surgery, particularly in cardiac surgery
- Adverse events in surgery are likely to be linked to several frequently recurrent, coincidental and cumulative human errors that are likely to happen because of threats that lie in the system rather than because of individual incompetence or negligence
- Some staff are reluctant to report incidents because they feel such information will be used badly or not used at all
- Staff said that improving communication would be the most effective way of improving patient safety.

Conclusions, recommendations and implications for practice and policy:
- Non-technical performance of healthcare staff should be assessed alongside technical performance in the future because the former can have a significant impact on how successful surgery is. Future research could look into developing suitable assessment scales for non-technical performance
- The opportunity for errors should be reduced by using things like checklists and standard
operating procedures to promote consistency of care, and discourage interruptions, absences and violations of safety practice

- Future researchers could look into using computer simulation methods more as these have the potential to work well alongside other methods of studying errors in healthcare

- Safety managers should ensure that healthcare staff are involved in the analysis and feedback of incident reports – this could encourage more comprehensive patient safety related reporting

- Useful lessons could be learned by NHS organisations from consulting and working with other industries and safety specialists

- Future research could look into evaluating the worth of pre-operation briefings and post-operation debriefings as a way of improving patient safety

- Efforts should continue into understanding the how, why, and when errors happen in operating theatres and the ethical and cultural barriers to effective safety research should be examined further and removed when possible.
Further Information

The full report, this research summary and details of other Patient Safety Research Portfolio work can be seen at [http://www.pcpoh.bham.ac.uk/publichealth/psrp/commissioned.shtml](http://www.pcpoh.bham.ac.uk/publichealth/psrp/commissioned.shtml)

About the Patient Safety Research Portfolio:
The Patient Safety Research Portfolio (PSRP) was created in 2001 as a programme to promote research into patient safety. It followed a report published by chief medical officer Sir Liam Donaldson in 2000 that looked at learning from adverse events in the NHS. The PSRP is funded by the Policy Research Programme at the Department of Health and reports directly to the CMO. The programme has also commissioned research on behalf of the National Patient Safety Agency (NPSA).

It funds research aimed at reducing errors that lead to bad outcomes for patients by:

- measuring the types and frequency of error
- analysing root causes to identify problems and how lessons can be learned
- specifying and testing interventions
- making sure that useful findings from research are distributed widely across the country

The programme is based at the University of Birmingham’s Department of Public Health and Epidemiology and is directed by Professor Richard Lilford. The PSRP team has a history of building capacity in the area of patient safety and is currently involved in evaluating The Health Foundation’s [Safer Patients Initiative](http://www.saferpatients.org.uk) and has recently published a series of papers on methods for patient safety research. The views expressed in this publication are those of the authors and not necessarily those of the PSRP, the Department of Health or the NPSA.

For further information about the PSRP visit our website at [http://www.pcpoh.bham.ac.uk/publichealth/psrp/](http://www.pcpoh.bham.ac.uk/publichealth/psrp/) or contact:

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